Calendar No. 457

103D CONGRESS
2D SESSION

S. 2153

To improve access to quality health care, to reform medical malpractice liability standards, to reduce paperwork and simplify administration of health care claims, to establish safe harbors from the application of the antitrust laws for certain activities of providers of health care services, to prevent fraud and abuse in the health care delivery system, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 25 (legislative day, MAY 16), 1994

Mr. KEMPTHORNE (for himself, Mr. CRAIG, and Mr. WALLOP) introduced the following bill; which was read the first time

JUNE 7, 1994

Read the second time and placed on the calendar

A BILL

To improve access to quality health care, to reform medical malpractice liability standards, to reduce paperwork and simplify administration of health care claims, to establish safe harbors from the application of the antitrust laws for certain activities of providers of health care services, to prevent fraud and abuse in the health care delivery system, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Advancement of Health Care Reform Act of 1994''.

(b) TABLE OF CONTENTS.—The table of contents is as follows:

SEC. 101. AMENDMENTS TO COBRA.

(a) LOWER COST COVERAGE OPTIONS.—Subparagraph (A) of section 4980B(f)(2) of the Internal Revenue Code of 1986 (relating to continuation coverage requirements of group health plans) is amended to read as follows:

''(A) TYPE OF BENEFIT COVERAGE.—The coverage must consist of coverage which, as of the time the coverage is being provided—

''(i) is identical to the coverage provided under the plan to similarly situated beneficiaries under the plan with respect to whom a qualifying event has not occurred,

''(ii) is so identical, except such coverage is offered with an annual $1,000 deductible, and

''(iii) is so identical, except such coverage is offered with an annual $3,000 deductible.

If coverage under the plan is modified for any group of similarly situated beneficiaries, the coverage shall also be modified in the same manner for all individuals who are qualified beneficiaries under the plan pursuant to this subsection in connection with such group.''.

(b) TERMINATION OF COBRA COVERAGE AFTER ELIGIBLE FOR EMPLOYER-BASED COVERAGE FOR 90 DAYS.—Clause (iv) of section 4980B(f)(2)(B) of the Internal Revenue Code of 1986 (relating to period of coverage) is amended—

(1) by striking ''or'' at the end of subclause (I);

(2) by redesignating subclause (II) as subclause (III); and

(3) by inserting after subclause (I) the following new subclause:

''(II) eligible for such employer-based coverage for more than 90 days, or''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to qualifying events occurring after the date of the enactment of this Act.

SEC. 102. PENALTY-FREE WITHDRAWALS FROM QUALIFIED RETIREMENT PLANS FOR COBRA COVERAGE.

(a) IN GENERAL.—Subparagraph (A) of section 72(t)(2) of the Internal Revenue Code of 1986 (relating to additional tax not to apply to certain distributions) is amended—

(1) by striking ''or'' at the end of clauses (iv) and (v);

(2) by striking the period at the end of clause (vi) and inserting '', or''; and

(3) by adding at the end the following new clause:

''(vii) made to an employee who is a qualified beneficiary during the period of continuation coverage under section 4980B(f).''

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to distributions made after the date of the enactment of this Act.

Subtitle B—Federally Qualified Health Insurance Plan

SEC. 111. FEDERALLY QUALIFIED HEALTH INSURANCE PLAN.

(a) IN GENERAL.—A federally qualified health insurance plan is a health insurance plan offered, issued, or renewed on or after January 1, 1997, which is certified by the applicable regulatory authority as meeting, at a minimum, the requirements of sections 112, 113, 114, and 115, and the regulatory program described in subtitle C.

(b) GENERAL DEFINITIONS.—Except as specifically provided otherwise, as used in this Act:

(1) HEALTH INSURANCE PLAN.—The term ''health insurance plan'' means any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization group contract and, in States which have distinct licensure requirements, a multiple employer welfare arrangement, but does not include any of the following offered by an insurer:

(A) Accident only, dental only, disability only, or long-term care only insurance.

(B) Coverage issued as a supplement to liability insurance.

(C) Workers' compensation or similar insurance.

(D) Automobile medical-payment insurance.

(2) APPLICABLE REGULATORY AUTHORITY.—The term ''applicable regulatory authority'' means—

(A) in the case of a State with a program described in subtitle C, the State commissioner or superintendent of insurance or other State authority responsible for regulation of health insurance; or

(B) if the State has not established such a program or such program has been decertified under section _____, the Secretary.

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(4) STATE.—The term ''State'' means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

SEC. 112. FAMILY SECURITY BENEFITS PACKAGE.

(a) IN GENERAL.—The requirements of this section are met, if the health insurance plan—

(1) provides coverage for all medically necessary acute medical care described in subsection (b);

(2) does not exclude coverage for selected illnesses or selected treatments if consistent with medically accepted practices; and

(3) meets the patient cost sharing requirements of subsection (c).

(b) ACUTE MEDICAL CARE.—Coverage for all medically necessary acute medical care is described in this subsection if such coverage includes—

(1) physician services;

(2) inpatient, outpatient, and emergency hospital services and appropriate alternatives to hospitalization; and

(3) inpatient and outpatient prescription drugs.

Nothing in this subsection may be construed to require the inclusion of abortion services.

(c) COST SHARING REQUIREMENTS.—The requirements of this subsection are as follows:

(1) LIMITATION ON DEDUCTIBLES.—A health insurance plan shall not provide a deductible amount for benefits provided in any plan year that exceeds—

(A) with respect to benefits payable for items and services furnished to a single individ-

ual enrolled under the plan, for a plan year beginning in—

(i) a calendar year prior to 1998, $1,000; or

(ii) for a subsequent calendar year, the limitation specified in this subparagraph for the previous calendar year increased by the percentage increase in the consumer price index for all urban consumers (United States city average, as published by the Bureau of Labor Statistics) for the 12-month period ending on September 30 of the preceding calendar year; and

(B) with respect to benefits payable for items and services furnished to a family enrolled under the plan, for a plan year beginning in—

(i) a calendar year prior to 1998, $2,000 per family; or

(ii) for a subsequent calendar year, the limitation specified in this subparagraph for the previous calendar year increased by such percentage increase.

If the limitation computed under subparagraph (A)(ii) or (B)(ii) is not a multiple of $10, it

shall be rounded to the next highest multiple of $10.

(2) LIMITATION ON COPAYMENTS AND COINSURANCE.—

(A) IN GENERAL.—A health insurance plan may not require the payment of any copayment or coinsurance for an item or service for which coverage is required under this section after an individual or a family covered under the plan has incurred out-of-pocket expenses under the plan that are equal to the out-of-pocket limit for a plan year.

(B) LIMIT ON OUT-OF-POCKET EXPENSES.—As used in this paragraph—

(i) OUT-OF-POCKET EXPENSES DEFINED.—The term ''out-of-pocket expenses'' means, with respect to an individual or a family in a plan year, amounts payable under the plan as deductibles and coinsurance with respect to items and services provided under the plan and furnished in the plan year on behalf of the individual or the family covered under the plan.

(ii) OUT-OF-POCKET LIMIT DEFINED.—The term ''out-of-pocket limit'' means for a plan year beginning in—

(I) a calendar year prior to 1998, $5,000; or

(II) for a subsequent calendar year, the limit specified in this clause for the previous calendar year increased by the percentage increase in the consumer price index for all urban consumers (United States city average, as published by the Bureau of Labor Statistics) for the 12-month period ending on September 30 of the preceding calendar year.

If the limit computed under subclause (II) is not a multiple of $10, it shall be rounded to the next highest multiple of $10.

SEC. 113. RATING PRACTICES.

(a) IN GENERAL.—The requirements of this section are met, if, except as provided in subsection (b), the health insurance plan provides for—

(1) a variation in premium rates only on the basis of age, sex, and geography; and

(2) a charge of the same premium rates to new applicants and existing policyholders with the same age, sex, and geographic characteristics.

(b) INCENTIVE DISCOUNTS.—A plan may discount an individual's premium rate as an incentive for participating in a program, approved by the applicable regulatory authority to be offered in conjunction with the coverage, which has as its objective, one or more of the following:

(1) To promote healthy behavior.

(2) To prevent or delay the onset of illness.

(3) To provide for screening or early detection of illness.

SEC. 114. GUARANTEED ISSUE.

(a) IN GENERAL.—Except as provided in paragraph (2), in the case of applications made on and after January 1, 1998, the following rules apply:

(1) IN GENERAL.—The requirements of this section are met, if, except as provided in paragraph (2), the health insurance plan—

(A) provides guaranteed issue at standard rates to all applicants, and

(B) does not exclude from coverage, or limit coverage for, any preexisting medical condition of any applicant who, on the date the application is made, has been continuously insured

for a period of at least 1 year prior to the date of the application under one or more of the following health insurance plans or programs:

(i) Another federally qualified health insurance plan.

(ii) An employer-sponsored group health insurance plan in effect before the date of the enactment of this Act.

(iii) An individual health insurance plan in effect before such date.

(iv) A program described in—

(I) title XVIII or XIX of the Social Security Act;

(II) chapter 55 of title 10, United States Code;

(III) chapter 17 of title 38, United States Code;

(IV) chapter 89 of title 5, United States Code; or

(V) the Indian Health Care Improvement Act.

(2) BREAK IN COVERAGE.—In the case of an applicant who has not been continuously insured for a period of 1 year prior to the date the application is made, the health insurance plan may exclude from

coverage, or limit coverage for, any preexisting medical condition for a period no greater than the lesser of—

(A) the number of months immediately prior to the date of the application during which the individual was not insured since the illness or condition in question was first diagnosed; or

(B) 1 year.

(b) TRANSITION RULE.—In the case of applications made in 1997, the requirements of this section are met, if the health insurance plan—

(1) provides guaranteed issue at standard rates to all applicants, and

(2) does not exclude from coverage, or limit coverage for, any preexisting medical condition of any applicant.

SEC. 115. GUARANTEED RENEWABILITY.

The requirements of this section are met, if the health insurance plan provides the policyholder with a contractual right to renew the coverage which stipulates that the insurer cannot cancel or refuse to renew the coverage except for cases of—

(1) nonpayment of premiums by the policyholder; or

(2) fraud or misrepresentation by the policyholder.

Subtitle C—Certification Of Federally Qualified Health Insurance Plans

SEC. 121. ESTABLISHMENT OF REGULATORY PROGRAM FOR CERTIFICATION OF PLANS.

(a) IN GENERAL.—Each State shall establish no later than January 1, 1997, a regulatory program which meets the standards referred to in section 122.

(b) PERIODIC SECRETARIAL REVIEW OF STATE REGULATORY PROGRAM.—The Secretary periodically shall review each State regulatory program to determine if such program continues to meet and enforce the standards referred to in section 122. If the Secretary initially determines that a State regulatory program no longer meets and enforces such standards, the Secretary shall provide the State an opportunity to adopt a plan of correction that would bring such program into compliance with such standards. If the Secretary makes a final determination that the State regulatory program fails to meet and enforce such standards after such an opportunity, the Secretary shall decertify such program and assume responsibility with respect to health insurance plans in the State.

SEC. 122. STANDARDS FOR REGULATORY PROGRAMS.

(a) IN GENERAL.—The Secretary, in consultation with the National Association of Insurance Commissioners (hereafter in this section referred to as ''NAIC'') shall develop by not later than 1 year after the date of the enactment of this Act, in the form of model Acts and model regulations, State regulatory program standards which include—

(1) procedures for certifying that the requirements of subtitle B have been met by a health insurance plan applying for certification as a federally qualified health insurance plan;

(2) the requirements described in subsections (b), (c), and (d);

(3) requirements with respect to solvency standards and guaranty funds for carriers of federally qualified health insurance plans; and

(4) reporting requirements under which carriers report to the Internal Revenue Service regarding the acquisition and termination by individuals of coverage under federally qualified health insurance plans.

(b) PASSBACK OF CLAIMS AND PREMIUMS.—The requirements of this subsection are met, if, in the case of an applicant who has been continuously insured, as described in section 114(a)(1)(B), and is at the time of the

application receiving treatment for a preexisting medical condition—

(1) the federally qualified health insurance plan is allowed to pass back to the applicant's previous plan any claims relating to such condition, together with a portion of the premium; and

(2) such previous plan is required to pay such claims and premium incurred during the lesser of—

(A) the duration of the course of the treatment or spell of illness; or

(B) 2 years from the date at which coverage commenced under the federally qualified health insurance plan.

(c) MARKETING PRACTICES.—The requirements of this subsection are met, if the carrier offering the federally qualified health insurance plan retains the right to select agents with whom such plan contracts and to determine the amount and form of compensation to such agents, except that—

(1) if the carrier chooses to contract with an agent, the carrier may not terminate or refuse to renew the agency contract for any reason related to the age, sex, health status, claims experience, occupation, or geographic location of the insureds placed by the agent with such plan, and

(2) the carrier may not, directly or indirectly, enter into any contract, agreement, or arrangement with an agent that provides for, or results in, any consideration provided to such agent for the issuance or renewal of such a plan to vary on account of the age, sex, health status, claims experience, occupation, or geographic location of the insureds placed by the agent with such plan.

(d) RISK ADJUSTMENT OR REINSURANCE PROGRAMS.—The requirements of this subsection are met, if the carrier offering the federally qualified health insurance plan participates in a State-administered risk adjustment program (or, at the option of the State, a reinsurance program) designed to compensate for the potential occurrence of grossly disproportionate distributions of above-standard or below-standard insured risks among federally qualified health insurance plans.

(e) NONBINDING STANDARDS.—The Secretary, in consultation with NAIC, shall also develop within the 1-year period described in subsection (a), nonbinding standards for premium rating practices and guaranteed renewability of coverage which, if the insurer so elects, is more generous (additional benefits or lower cost sharing or both) than the requirements under subtitle B for federally qualified health insurance plans.

TITLE II—PAPERWORK REDUCTION AND ADMINISTRATIVE SIMPLIFICATION

SEC. 201. PREEMPTION OF STATE QUILL PEN LAWS.

After December 31, 1995, no effect shall be given to any provision of State law that requires medical or health insurance records (including billing information) to be maintained in written, rather than electronic, form.

SEC. 202. CONFIDENTIALITY OF ELECTRONIC HEALTH CARE INFORMATION.

(a) PROMULGATION OF REQUIREMENTS.—

(1) IN GENERAL.—The Secretary shall promulgate, and may modify from time to time, requirements to facilitate and ensure the uniform, confidential treatment of individually identifiable health care information in electronic environments.

(2) ITEMS TO BE INCLUDED.—The requirements under this subsection shall—

(A) provide for the preservation of confidentiality and privacy rights in electronic health care claims processing and payment;

(B) apply to the collection, storage, handling, and transmission of individually identifiable health care data (including initial and subsequent disclosures) in electronic form by health

plans, public and private third-party payers, providers of health care, and all other entities involved in the transactions;

(C) not apply to public health reporting required under Federal or State law;

(D) delineate protocols for securing electronic storage, processing, and transmission of health care data;

(E) specify fair information practices that assure a proper balance between required disclosures and use of data, including—

(i) creating a proper balance between what an individual is expected to divulge to a record-keeping organization and what the individual seeks in return;

(ii) minimizing the extent to which information concerning an individual is itself a source of unfairness in any decision made on the basis of such information; and

(iii) creating and defining obligations respecting the uses and disclosures that will be made of recorded information about an individual;

(F) require publication of the existence of health care data banks;

(G) establish appropriate protections for highly sensitive data (such as data concerning mental health, substance abuse, and communicable and genetic diseases);

(H) encourage the use of alternative dispute resolution mechanisms (where appropriate); and

(I) provide for the deletion of information that is no longer needed to carry out the purpose for which it was collected.

(3) CONSULTATION WITH WORKING GROUP.—In promulgating and modifying requirements under this subsection, the Secretary shall consult with a working group of knowledgeable individuals representing all interested parties (including third-party payers, providers, consumers, employers, information managers, and technical experts).

(4) DEADLINE.—The Secretary shall first promulgate requirements under this subsection by not later than 6 months after the date of the enactment of this Act.

(b) APPLICATION OF REQUIREMENTS.—

(1) STATE ENFORCEMENT OF SIMILAR REQUIREMENTS.—The requirements promulgated

under subsection (a) shall not apply to health care information in a State if—

(A) the State has applied to the Secretary for a determination that the State has in effect a law that provides for the application of requirements with respect to such information (and enforcement provisions with respect to such requirements) consistent with such requirements (and with the enforcement provisions of subsection (c)); and

(B) the Secretary determines that the State has such a law in effect.

(2) APPLICATION TO CURRENT INFORMATION.—The Secretary shall specify the extent to which (and manner in which) the requirements promulgated under subsection (a) apply to information collected before the effective date of the requirements.

(c) DEFENSE FOR PROPER DISCLOSURES.—An entity that establishes that it has disclosed health care information in accordance with the requirements promulgated under subsection (a) has established a defense in an action brought for improper disclosure of such information.

(d) PENALTIES FOR VIOLATIONS.—An entity that collects, stores, handles, transmits, or discloses health care

information in violation of the requirements promulgated under subsection (a) is liable for civil damages, equitable remedies, and attorneys' fees (if appropriate), in accordance with regulations of the Secretary.

SEC. 203. STANDARDIZATION FOR THE ELECTRONIC RECEIPT AND TRANSMISSION OF HEALTH PLAN INFORMATION.

(a) GOALS.—The Secretary shall establish national goals, and time frameworks, respecting the progress to be made by the health care industry in eliminating unnecessary paperwork and achieving appropriate standardization in the areas of electronic receipt and transmission of health care claims and health plan information and eligibility verification (consistent with the requirements promulgated under section 202(a)).

(b) CONTINGENT REQUIREMENTS.—If the Secretary determines that the health care industry has failed to meet the goals established under subsection (a) by the deadlines established by the Secretary under such subsection, the Secretary shall promulgate (and may, from time to time, modify) standards and requirements concerning the electronic receipt and transmission of health plan claims forms and other health plan information.

(c) COMPLIANCE.—

(1) IN GENERAL.—The Secretary may impose a civil money penalty on any health plan (other than a health plan described in paragraph (2)) that fails to comply with standards and requirements promulgated under subsection (b) in an amount not to exceed $100 for each such failure. The provisions of section 1128A of the Social Security Act (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

(2) PLANS SUBJECT TO EFFECTIVE STATE REGULATION.—A health plan described in this paragraph is a health plan that is subject to regulation by a State, if the Secretary finds that—

(A) the State provides for application of the standards and requirements promulgated under subsection (b); and

(B) the State regulatory program provides for the appropriate and effective enforcement of such standards and requirements with respect to such plans.

(d) CONSULTATION.—The Secretary shall conduct activities under this section in consultation with the Ac-

credited Standards Committee X–12 of the American National Standards Institute, insurers, providers, and others.

SEC. 204. USE OF UNIFORM HEALTH CLAIMS FORMS AND IDENTIFICATION NUMBERS.

(a) GOALS.—The Secretary shall establish national goals, and time frameworks, respecting the progress to be made by the health care industry in achieving uniformity—

(1) in the format and content of basic claims forms under health plans, and

(2) in the use of common identification numbers for beneficiaries and providers of health care items or services under health plans.

(b) CONTINGENT REQUIREMENTS.—If the Secretary determines that the health care industry has failed to meet the goals established under subsection (a) by the deadlines established by the Secretary under such subsection, the Secretary shall promulgate (and may, from time to time, modify) standards and requirements concerning—

(1) the format and content of basic claims forms under health plans; and

(2) the common identification numbers to be used by health plans to identify health plan beneficiaries and health care providers.

(c) COMPLIANCE.—

(1) IN GENERAL.—The Secretary may impose a civil money penalty on any health plan (other than a health plan described in paragraph (2)) that fails to comply with standards and requirements promulgated under subsection (b) in an amount not to exceed $100 for each such failure. The provisions of section 1128A of the Social Security Act (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

(2) PLANS SUBJECT TO EFFECTIVE STATE REGULATION.—A health plan described in this paragraph is a health plan that is subject to regulation by a State, if the Secretary finds that—

(A) the State provides for application of the standards and requirements promulgated under subsection (b); and

(B) the State regulatory program provides for the appropriate and effective enforcement of such standards and requirements with respect to such plans.

(d) CONSULTATION.—The Secretary shall conduct activities under this section in consultation with the

Workgroup for Electronic Data Interchange and with insurers, providers, and others.

SEC. 205. PRIORITY AMONG INSURERS.

(a) GOALS.—The Secretary shall establish national goals, and time frameworks, respecting the progress to be made by the health care industry in achieving uniformity in the rules for determining the liability of insurers when benefits are payable under two or more health plans.

(b) CONTINGENT REQUIREMENTS.—If the Secretary determines that the health care industry has failed to meet the goals established under subsection (a) by the deadlines established by the Secretary under such subsection, the Secretary shall promulgate (and may, from time to time, modify) rules for determining the liability of health plans when benefits are payable under two or more health plans.

(c) COMPLIANCE.—

(1) IN GENERAL.—The Secretary may impose a civil money penalty on any health plan (other than a health plan described in paragraph (2)) that fails to comply with rules promulgated under subsection (b) in an amount not to exceed $100 for each such failure. The provisions of section 1128A of the Social Security Act (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under this paragraph

in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

(2) PLANS SUBJECT TO EFFECTIVE STATE REGULATION.—A health plan described in this paragraph is a health plan that is subject to regulation by a State, if the Secretary finds that—

(A) the State provides for application of the rules established under subsection (b); and

(B) the State regulatory program provides for the appropriate and effective enforcement of such rules with respect to such plans.

(d) CONSULTATION.—The Secretary shall conduct activities under this section in consultation with health plans.

SEC. 206. FURNISHING OF INFORMATION AMONG HEALTH PLANS.

(a) GOALS.—The Secretary shall establish national goals, and time frameworks, respecting the progress to be made by the health care industry in achieving uniformity in the availability of information among health plans when benefits are payable under two or more health plans.

(b) CONTINGENT REQUIREMENTS.—If the Secretary determines that the health care industry has failed to meet the goals established under subsection (a) by the deadlines

established by the Secretary under such subsection, the Secretary shall promulgate (and may, from time to time, modify) requirements concerning the transfer among health plans (and annual updating) of appropriate information (which may include requirements for the use of unique identifiers, and for the listing of all individuals covered under a health plan).

(c) COMPLIANCE.—

(1) IN GENERAL.—The Secretary may impose a civil money penalty on any health plan (other than a health plan described in paragraph (2)) that fails to comply with requirements promulgated under subsection (b) in an amount not to exceed $100 for each such failure. The provisions of section 1128A of the Social Security Act (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act.

(2) PLANS SUBJECT TO EFFECTIVE STATE REGULATION.—A plan described in this paragraph is a health plan that is subject to regulation by a State, if the Secretary finds that—

(A) the State provides for application of the requirements promulgated under subsection (b); and

(B) the State regulatory program provides for the appropriate and effective enforcement of such requirements with respect to such plans.

(d) CONSULTATION.—The Secretary shall conduct activities under this section in consultation with health plans.

SEC. 207. DEFINITIONS.

As used in this title:

(1) HEALTH PLAN.—The term ''health plan'' means any contract or arrangement under which an entity bears all or part of the cost of providing health care items and services, including a hospital or medical expense incurred policy or certificate, hospital or medical service plan contract, or health maintenance subscriber contract (including any closed accountable health plan), but does not include (except for purposes of sections 205 and 206)—

(A) coverage only for accident, dental, vision, disability, or long term care, medicare supplemental health insurance, or any combination thereof,

(B) coverage issued as a supplement to liability insurance,

(C) workers' compensation or similar insurance; or

(D) automobile medical-payment insurance.

(2) PROVIDER.—The term ''provider'' means a physician, hospital, pharmacy, laboratory, or other person licensed or otherwise authorized under applicable State laws to furnish health care items or services.

TITLE III—HEALTH CARE LIABILITY REFORM

Subtitle A—General Provisions

SEC. 301. FEDERAL REFORM OF MEDICAL MALPRACTICE LIABILITY ACTIONS.

(a) APPLICABILITY.—This title shall apply with respect to any medical malpractice liability claim and to any medical malpractice liability action brought in any Federal or State court, except that this title shall not apply to a claim or action for damages arising from a vaccine-related injury or death to the extent that title XXI of the Public Health Service Act applies to the claim or action.

(b) PREEMPTION.—The provisions of this title shall preempt any State law to the extent such law is inconsist-

ent with the limitations contained in such provisions. The provisions of this title shall not preempt any State law that provides for defenses or places limitations on a person's liability in addition to those contained in this title, places greater limitations on the amount of attorneys' fees that can be collected, or otherwise imposes greater restrictions than those provided in this title.

(c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE OF LAW OR VENUE.—

Nothing in subsection (b) shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any provision of law;

(2) waive or affect any defense of sovereign immunity asserted by the United States;

(3) affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976;

(4) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation; or

(5) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum.

(d) FEDERAL COURT JURISDICTION NOT ESTABLISHED ON FEDERAL QUESTION GROUNDS.—Nothing in this title shall be construed to establish any jurisdiction in the district courts of the United States over medical malpractice liability actions on the basis of section 1331 or 1337 of title 28, United States Code.

SEC. 302. DEFINITIONS.

As used in this title:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system established under this title that provides for the resolution of medical malpractice liability claims in a manner other than through medical malpractice liability actions.

(2) CLAIMANT.—The term ''claimant'' means any person who alleges a medical malpractice liability claim, and any person on whose behalf such a claim is alleged, including the decedent in the case of an action brought through or on behalf of an estate.

(3) CLEAR AND CONVINCING EVIDENCE.—The term ''clear and convincing evidence'' is that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to

the truth of the allegations sought to be established, except that such measure or degree of proof is more than that required under preponderance of the evidence, but less than that required for proof beyond a reasonable doubt.

(4) ECONOMIC DAMAGES.—The term ''economic damages'' means damages paid to compensate an individual for hospital and other medical expenses, lost wages, lost employment, and other pecuniary losses.

(5) HEALTH CARE PROFESSIONAL.—The term ''health care professional'' means any individual who provides health care services in a State and who is required by the laws or regulations of the State to be licensed or certified by the State to provide such services in the State.

(6) HEALTH CARE PROVIDER.—The term ''health care provider'' means any organization or institution that is engaged in the delivery of health care services in a State and that is required by the laws or regulations of the State to be licensed or certified by the State to engage in the delivery of such services in the State.

(7) INJURY.—The term ''injury'' means any illness, disease, or other harm that is the subject of

a medical malpractice liability action or a medical malpractice liability claim.

(8) MEDICAL MALPRACTICE LIABILITY ACTION.—The term ''medical malpractice liability action'' means a civil action brought in a Federal or State court against a health care provider or health care professional in which the plaintiff alleges a medical malpractice liability claim, but does not include any action in which the plaintiff's sole allegation is an allegation of an intentional tort.

(9) MEDICAL MALPRACTICE LIABILITY CLAIM.—The term ''medical malpractice liability claim'' means a claim in which the claimant alleges that injury was caused by the provision of (or the failure to provide) health care services or the use of a medical product.

(10) MEDICAL PRODUCT.—

(A) IN GENERAL.—The term ''medical product'' means, with respect to the allegation of a claimant, a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) or a medical device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) if—

(i) such drug or device was subject to premarket approval under section 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 357, or 360e) or section 351 of the Public Health Service Act (42 U.S.C. 262) with respect to the safety of the formulation or performance of the aspect of such drug or device which is the subject of the claimant's allegation or the adequacy of the packaging or labeling of such drug or device, and such drug or device is approved by the Food and Drug Administration; or

(ii) the drug or device is generally recognized as safe and effective under regulations issued by the Secretary under section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)).

(B) EXCEPTION IN CASE OF MISREPRESENTATION OR FRAUD.—Notwithstanding subparagraph (A), the term ''medical product'' shall not include any product described in such subparagraph if the claimant shows that the product is approved by the Food and Drug Administration for marketing as a result of with-

held information, misrepresentation, or an illegal payment by manufacturer of the product.

(11) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages paid to compensate an individual for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of consortium, and other nonpecuniary losses, but does not include punitive damages.

(12) PUNITIVE DAMAGES; EXEMPLARY DAMAGES.—The terms ''punitive damages'' and ''exemplary damages'' mean compensation, in addition to compensation for actual harm suffered, that is awarded for the purpose of punishing a person for conduct deemed to be malicious, wanton, willful, or excessively reckless.

(13) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

SEC. 303. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided in subsection (b) and section 318(c), this title shall apply with respect to claims accruing or actions brought on or after the expi-

ration of the 3-year period that begins on the date of the enactment of this Act.

(b) EXCEPTION FOR STATES REQUESTING EARLIER IMPLEMENTATION OF REFORMS.—

(1) APPLICATION.—A State may submit an application to the Secretary requesting the early implementation of this subtitle with respect to claims or actions brought in the State.

(2) DECISION BY SECRETARY.—The Secretary shall issue a response to a State's application under paragraph (1) not later than 90 days after receiving the application. If the Secretary determines that the State meets the requirements of this title at the time of submitting its application, the Secretary shall approve the State's application, and this title shall apply with respect to actions brought in the State on or after the expiration of the 90-day period that begins on the date the Secretary issues the response. If the Secretary denies the State's application, the Secretary shall provide the State with a written explanation of the grounds for the decision.

Subtitle B—Medical Malpractice and Product Liability Reform

SEC. 311. REQUIREMENT FOR INITIAL RESOLUTION OF ACTION THROUGH ALTERNATIVE DISPUTE RESOLUTION.

(a) IN GENERAL.—

(1) STATE CASES.—A medical malpractice liability action may not be brought in any State court during a calendar year unless the medical malpractice liability claim that is the subject of the action has been initially resolved under an alternative dispute resolution system certified for the year by the Secretary under section 332(a), or, in the case of a State in which such a system is not in effect for the year, under the alternative Federal system established under section 332(b).

(2) FEDERAL DIVERSITY ACTIONS.—A medical malpractice liability action may not be brought in any Federal court under section 1332 of title 28, United States Code, during a calendar year unless the medical malpractice liability claim that is the subject of the action has been initially resolved under the alternative dispute resolution system referred to in paragraph (1) that applied in the State whose law applies in such action.

(3) CLAIMS AGAINST UNITED STATES.—

(A) ESTABLISHMENT OF PROCESS FOR CLAIMS.—The Attorney General shall establish an alternative dispute resolution process for the resolution of tort claims consisting of medical malpractice liability claims brought against the United States under chapter 171 of title 28, United States Code. Under such process, the resolution of a claim shall occur after the completion of the administrative claim process applicable to the claim under section 2675 of such title.

(B) REQUIREMENT FOR INITIAL RESOLUTION UNDER PROCESS.—A medical malpractice liability action based on a medical malpractice liability claim described in subparagraph (A) may not be brought in any Federal court unless the claim has been initially resolved under the alternative dispute resolution process established by the Attorney General under such subparagraph.

(b) INITIAL RESOLUTION OF CLAIMS UNDER ADR.—For purposes of subsection (a), an action is ''initially resolved'' under an alternative dispute resolution system if—

(1) the ADR reaches a decision on whether the defendant is liable to the plaintiff for damages; and

(2) if the ADR determines that the defendant is liable, the ADR reaches a decision on the amount of damages assessed against the defendant.

(c) PROCEDURES FOR FILING ACTIONS.—

(1) NOTICE OF INTENT TO CONTEST DECISION.—Not later than 60 days after a decision is issued with respect to a medical malpractice liability claim under an alternative dispute resolution system, each party affected by the decision shall submit a sealed statement to a court of competent jurisdiction indicating whether or not the party intends to contest the decision.

(2) DEADLINE FOR FILING ACTION.—A medical malpractice liability action may not be brought by a party unless—

(A) the party has filed the notice of intent required by paragraph (1); and

(B) the party files the action in a court of competent jurisdiction not later than 90 days after the decision resolving the medical malpractice liability claim that is the subject of the action is issued under the applicable alternative dispute resolution system.

(3) COURT OF COMPETENT JURISDICTION.—For purposes of this subsection, the term ''court of competent jurisdiction'' means—

(A) with respect to actions filed in a State court, the appropriate State trial court; and

(B) with respect to actions filed in a Federal court, the appropriate United States district court.

(d) LEGAL EFFECT OF UNCONTESTED ADR DECISION.—The decision reached under an alternative dispute resolution system shall, for purposes of enforcement by a court of competent jurisdiction, have the same status in the court as the verdict of a medical malpractice liability action adjudicated in a Federal or State trial court. The previous sentence shall not apply to a decision that is contested by a party affected by the decision pursuant to subsection (c)(1).

SEC. 312. CALCULATION AND PAYMENT OF DAMAGES.

(a) LIMITATION ON NONECONOMIC DAMAGES.—

(1) IN GENERAL.—Except as provided in paragraph (2), the total amount of damages that may be awarded to an individual and the family members of such individual for noneconomic losses resulting from an injury which is the subject of a health care malpractice claim or a health care product liability

claim may not exceed $250,000, regardless of the number of defendants against whom the claim is brought, the number of claims brought with respect to the injury, or the number of actions brought with respect to the injury.

(2) JURY TRIALS.—

(A) REDUCTION IN AWARDS.—Any jury trial with respect to involving a medical malpractice liability claim, the jury shall not be informed of the limitation established under paragraph (1). If the jury awards an amount for noneconomic damages that exceeds $250,000, the court shall reduce the award to $250,000 unless the court finds that special circumstances (such as egregious injury) would make such reduction unjust.

(B) DISCRETION OF COURT.—In any case in which the court finds a reduction under subparagraph (A) would be unjust, the court may—

(i) decline to reduce such award; or

(ii) reduce such award by a lesser amount than provided for under subparagraph (A).

(b) MANDATORY OFFSETS FOR DAMAGES PAID BY A COLLATERAL SOURCE.—

(1) IN GENERAL.—With respect to a health care malpractice claim or action, the total amount of damages received by an individual under such action shall be reduced, in accordance with paragraph (2), by any other payment that has been, or will be, made to an individual to compensate such individual for the injury that was the subject of such action.

(2) AMOUNT OF REDUCTION.—The amount by which an award of damages to an individual for an injury shall be reduced under paragraph (1) shall be—

(A) the total amount of any payments (other than such award) that have been made or that will be made to such individual to pay costs of or compensate such individual for the injury that was the subject of the action; minus

(B) the amount paid by such individual (or by the spouse, parent, or legal guardian of such individual) to secure the payments described in subparagraph (A).

(c) TREATMENT OF PUNITIVE DAMAGES.—

(1) BASIS FOR RECOVERY.—Punitive or exemplary damages shall not be awarded in a medical

malpractice liability action unless the claimant establishes by clear and convincing evidence that the injury suffered was the direct result of conduct manifesting a malicious, wanton, willful, or excessively reckless disregard of the safety of others.

(2) NO AWARD AGAINST MANUFACTURER OF MEDICAL PRODUCT.—In the case of a medical malpractice liability action in which the plaintiff alleges a claim against the manufacturer of a medical product, no punitive or exemplary damages may be awarded against such manufacturer.

(3) PAYMENTS TO STATE FOR MEDICAL QUALITY ASSURANCE ACTIVITIES.—

(A) IN GENERAL.—Any punitive or exemplary damages awarded in a medical malpractice liability action shall be paid to the State in which the action is brought or, in a case brought in Federal court, to the State in which the health care services that caused the injury that is the subject of the action were provided.

(B) ACTIVITIES DESCRIBED.—A State shall use amounts paid pursuant to subparagraph (A) to carry out activities to assure the safety and quality of health care services pro-

vided in the State, including (but not limited to)—

(i) licensing or certifying health care professionals and health care providers in the State;

(ii) operating alternative dispute resolution systems;

(iii) carrying out public education programs relating to medical malpractice and the availability of alternative dispute resolution systems in the State; and

(iv) carrying out programs to reduce malpractice-related costs for retired providers or other providers volunteering to provide services in medically underserved areas.

(C) MAINTENANCE OF EFFORT.—A State shall use any amounts paid pursuant to subparagraph (A) to supplement and not to replace amounts expended by the State for the activities described in subparagraph (B).

(d) PERIODIC PAYMENTS FOR FUTURE LOSSES.—

(1) GENERAL RULE.—In any medical malpractice liability action in which the damages awarded for future economic loss exceeds $100,000, a de-

fendant may not be required to pay such damages in a single, lump-sum payment, but shall be permitted to make such payments periodically based on when the damages are found likely to occur, as such payments are determined by the court.

(2) WAIVER.—A court may waive the application of paragraph (1) with respect to a defendant if the court determines that it is not in the best interests of the plaintiff to receive payments for damages on such a periodic basis.

SEC. 313. TREATMENT OF ATTORNEY'S FEES AND OTHER COSTS.

(a) LIMITATION ON AMOUNT OF CONTINGENCY FEES.—

(1) IN GENERAL.—An attorney who represents, on a contingency fee basis, a claimant in a medical malpractice liability claim may not charge, demand, receive, or collect for services rendered in connection with such claim in excess of the following amount recovered by judgment or settlement under such claim:

(A) 25 percent of the first $150,000 (or portion thereof) recovered, plus

(B) 10 percent of any amount in excess of $150,000 recovered.

(2) CALCULATION OF PERIODIC PAYMENTS.—In the event that a judgment or settlement includes periodic or future payments of damages, the amount recovered for purposes of computing the limitation on the contingency fee under paragraph (1) shall be based on the cost of the annuity or trust established to make the payments. In any case in which an annuity or trust is not established to make such payments, such amount shall be based on the present value of the payments.

(b) REQUIRING PARTY CONTESTING ADR RULING TO PAY ATTORNEY'S FEES AND OTHER COSTS.—

(1) IN GENERAL.—The court in a medical malpractice liability action shall require the party that (pursuant to section 311(c)(1)) contested the ruling of the alternative dispute resolution system with respect to the medical malpractice liability claim that is the subject of the action to pay to the opposing party the costs incurred by the opposing party under the action, including attorney's fees, fees paid to expert witnesses, and other litigation expenses (but not including court costs, filing fees, or other expenses paid directly by the party to the court, or any fees or costs associated with the resolution of the claim

under the alternative dispute resolution system), but only if—

(A) in the case of an action in which the party that contested the ruling is the claimant, the amount of damages awarded to the party under the action does not exceed the amount of damages awarded to the party under the ADR system by at least 10 percent; and

(B) in the case of an action in which the party that contested the ruling is the defendant, the amount of damages assessed against the party under the action is not at least 10 percent less than the amount of damages assessed under the ADR system.

(2) EXCEPTIONS.—Paragraph (1) shall not apply if—

(A) the party contesting the ruling made under the previous alternative dispute resolution system shows that—

(i) the ruling was procured by corruption, fraud, or undue means;

(ii) there was partiality or corruption under the system;

(iii) there was other misconduct under the system that materially prejudiced the party's rights; or

(iv) the ruling was based on an error of law;

(B) the party contesting the ruling made under the alternative dispute resolution system presents new evidence before the trier of fact that was not available for presentation under the ADR system;

(C) the medical malpractice liability action raised a novel issue of law; or

(D) the court finds that the application of such paragraph to a party would constitute an undue hardship, and issues an order waiving or modifying the application of such paragraph that specifies the grounds for the court's decision.

(3) REQUIREMENT FOR PERFORMANCE BOND.—The court in a medical malpractice liability action shall require the party that (pursuant to section 311(c)(1)) contested the ruling of the alternative dispute resolution system with respect to the medical malpractice liability claim that is the subject of the action to post a performance bond (in such

amount and consisting of such funds and assets as the court determines to be appropriate), except that the court may waive the application of such requirement to a party if the court determines that the posting of such a bond is not necessary to ensure that the party shall meet the requirements of this subsection to pay the opposing party the costs incurred by the opposing party under the action.

(4) LIMIT ON ATTORNEY'S FEES PAID.—Attorneys' fees that are required to be paid under paragraph (1) by the contesting party shall not exceed the amount of the attorneys' fees incurred by the contesting party in the action. If the attorneys' fees of the contesting party are based on a contingency fee agreement, the amount of attorneys' fees for purposes of the preceding sentence shall not exceed the reasonable value of those services.

(5) RECORDS.—In order to receive attorneys' fees under paragraph (1), counsel of record in the medical malpractice liability action involved shall maintain accurate, complete records of hours worked on the action, regardless of the fee arrangement with the client involved.

(c) FRIVOLOUS ACTIONS.—

(1) BY ATTORNEY.—With respect to a health care malpractice claim or action, if the court or the adjudicating body determines that the claim or action, or any part thereof, was pursued by an attorney where the attorney does not have reasonable grounds to believe that the action was well grounded in fact and was warranted by existing law, the court shall impose an appropriate sanction, including the reasonable costs and attorneys fees attributable to the frivolous claims.

(2) BY CLAIMANT.—Sanctions under paragraph (1) may apply against a claimant if the court determines that the frivolous nature of the action was a result of the misrepresentation of facts by the claimant to the attorney.

(d) CONTINGENCY FEE DEFINED.—As used in this section, the term ''contingency fee'' means any fee for professional legal services which is, in whole or in part, contingent upon the recovery of any amount of damages, whether through judgment or settlement.

SEC. 314. JOINT AND SEVERAL LIABILITY.

(a) IN GENERAL.—Except as provided in Section 313(b), a defendant may be held severally but not jointly liable in a medical malpractice action. A person found liable for damages in any such action may be found liable,

if at all, only for those damages directly attributable to the person's proportionate share of fault or responsibility for the injury, and may not be found liable for damages attributable to the proportionate share of fault or responsibility of any other person (without regard to whether that person is a party to the action) for the injury, including any person bringing the action.

(b) DETERMINATION OF PROPORTION OF RESPONSIBILITY.—For purposes of this subsection, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. 315. STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Except as provided in paragraph (2), no health care malpractice claim or action may be initiated after the expiration of the 2-year period that begins on the date on which the alleged injury and its cause should reasonably have been discovered, but in no event later than 6 years after the date of the alleged occurrence of the injury.

(2) EXCEPTION FOR MINORS.—In the case of an alleged injury suffered by a minor who has not attained 6 years of age, no health care malpractice claim or action may be initiated after the expiration of the 2-year period that begins on the date on which the alleged injury and its cause should reasonably have been discovered, but in

no event later than 6 years after the date of the alleged occurrence of the injury and its cause or the date on which the minor attains 12 years of age, whichever is later.

SEC. 316. PRACTICE GUIDELINES.

(a) REBUTTABLE PRESUMPTION.—

(1) DEVELOPMENT.—Each State shall develop, for certification by the Secretary, a set of specialty clinical practice guidelines, based on recommended guidelines developed by the Agency for Health Care Policy and Research.

(2) PROVISION OF HEALTH CARE UNDER GUIDELINES.—Notwithstanding any other provision of law, in any claim or action brought in a Federal or State court or other forum arising from the provision of a health care service to an individual, if the service was provided to the individual in accordance with the guidelines developed by the State (that certified or regulates the health plan involved in the action) and certified by the Secretary under paragraph (1), the guidelines—

(A) may be introduced by a provider who is a party to the claim or action;

(B) if introduced, shall establish a rebuttable presumption that the service prescribed by

the guidelines is the appropriate standard of medical care; and

(C) if used to establish a rebuttable presumption, may only be overcome by the presentation of clear and convincing evidence on behalf of the party against whom the presumption operates.

(b) ABSOLUTE DEFENSE.—With respect to new or experimental treatments that are part of approved research trials (as defined in subsection (c)), no health care provider may be required to provide or held liable for failing to provide such treatment until that treatment is found to be safe and efficacious by the Agency for Health Care Policy and Research.

(c) DEFINITIONS.—As used in this section—

(1) APPROVED RESEARCH TRIALS.—The term ''approved research trial'' means a trial—

(A) conducted for the primary purpose of determining the safety, effectiveness, efficacy, or health outcomes of a treatment, compared with the best available alternative treatment; and

(B) approved by the Secretary.

A trial is deemed to be approved under this subparagraph if it is approved by the National Institutes of Health, the

Food and Drug Administration (through an investigational new drug exemption), the Department of Defense, the Department of Veterans Affairs, or by a qualified nongovernmental research entity (as identified in guidelines issued by one or more of the National Institutes of Health).

(2) NEW OR EXPERIMENTAL TREATMENTS.—The term ''new or experimental treatments'' means a treatment for which there is not sufficient evidence to determine the health outcome of the treatment compared with the best available alternative treatment (or with no treatment if there is no alternative treatment).

SEC. 317. UNIFORM STANDARD FOR DETERMINING NEGLIGENCE.

A defendant in a medical malpractice liability action may not be found to have acted negligently unless the defendant's conduct at the time of providing the health care services that are the subject of the action was not reasonable.

SEC. 318. SPECIAL PROVISION FOR CERTAIN OBSTETRIC SERVICES.

(a) IMPOSITION OF HIGHER STANDARD OF PROOF.—In the case of a medical malpractice liability claim relating to services provided during labor or the delivery of a baby,

if the health care professional against whom the claim is brought did not previously treat the individual alleged to have been injured for the pregnancy, the trier of fact may not find that the defendant committed malpractice and may not assess damages against the health care professional unless the malpractice is proven by clear and convincing evidence.

(b) APPLICABILITY TO GROUP PRACTICES OR AGREEMENTS AMONG PROVIDERS.—For purposes of subsection (a), a health care professional shall be considered to have previously treated an individual for a pregnancy if the professional is a member of a group practice whose members previously treated the individual for the pregnancy or is providing services to the individual during labor or the delivery of a baby pursuant to an agreement with another health care professional.

(c) EFFECTIVE DATE.—This section shall apply with respect to claims accruing or actions brought on or after the expiration of the 2-year period that begins on the date of the enactment of this Act.

Subtitle C—Requirements for State Alternative Dispute Resolution Systems (ADR)

SEC. 331. BASIC REQUIREMENTS.

(a) IN GENERAL.—A State's alternative dispute resolution system meets the requirements of this section if the system—

(1) applies to all medical malpractice liability claims under the jurisdiction of the courts of that State;

(2) requires that a written opinion resolving the dispute be issued not later than 6 months after the date by which each party against whom the claim is filed has received notice of the claim (other than in exceptional cases for which a longer period is required for the issuance of such an opinion), and that the opinion contains—

(A) findings of fact relating to the dispute, and

(B) a description of the costs incurred in resolving the dispute under the system (including any fees paid to the individuals hearing and resolving the claim), together with an appropriate assessment of the costs against any of the parties;

(3) requires individuals who hear and resolve claims under the system to meet such qualifications as the State may require (in accordance with regulations of the Secretary);

(4) is approved by the State or by local governments in the State;

(5) with respect to a State system that consists of multiple dispute resolution procedures—

(A) permits the parties to a dispute to select the procedure to be used for the resolution of the dispute under the system; and

(B) if the parties do not agree on the procedure to be used for the resolution of the dispute, assigns a particular procedure to the parties;

(6) provides for the transmittal to the State agency responsible for monitoring or disciplining health care professionals and health care providers of any findings made under the system that such a professional or provider committed malpractice, unless, during the 90-day period beginning on the date the system resolves the claim against the professional or provider, the professional or provider brings an action contesting the decision made under the system; and

(7) provides for the regular transmittal to the Administrator for Health Care Policy and Research of information on disputes resolved under the system, in a manner that assures that the identity of the parties to a dispute shall not be revealed.

(b) APPLICATION OF MALPRACTICE LIABILITY STANDARDS TO ALTERNATIVE DISPUTE RESOLUTION.—The provisions of subtitle B shall apply with respect to claims brought under a State alternative dispute resolution system or the alternative Federal system in the same manner as such provisions apply with respect to medical malpractice liability actions brought in the State.

SEC. 332. CERTIFICATION OF STATE SYSTEMS; APPLICABILITY OF ALTERNATIVE FEDERAL SYSTEM.

(a) CERTIFICATION.—

(1) IN GENERAL.—Not later than October 1 of each year (beginning with 1994), the Secretary, in consultation with the Attorney General, shall determine whether a State's alternative dispute resolution system meets the requirements of this subtitle for the following calendar year.

(2) BASIS FOR CERTIFICATION.—The Secretary shall certify a State's alternative dispute resolution system under this subsection for a calendar year if

the Secretary determines under paragraph (1) that the system meets the requirements of section 331.

(b) APPLICABILITY OF ALTERNATIVE FEDERAL SYSTEM.—

(1) ESTABLISHMENT AND APPLICABILITY.—Not later than October 1, 1994, the Secretary, in consultation with the Attorney General, shall establish by rule an alternative Federal ADR system for the resolution of medical malpractice liability claims during a calendar year in States that do not have in effect an alternative dispute resolution system certified under subsection (a) for the year.

(2) REQUIREMENTS FOR SYSTEM.—Under the alternative Federal ADR system established under paragraph (1)—

(A) paragraphs (1), (2), (6), and (7) of section 331(a) shall apply to claims brought under the system;

(B) if the system provides for the resolution of claims through arbitration, the claims brought under the system shall be heard and resolved by arbitrators appointed by the Secretary in consultation with the Attorney General; and

(C) with respect to a State in which the system is in effect, the Secretary may (at the State's request) modify the system to take into account the existence of dispute resolution procedures in the State that affect the resolution of medical malpractice liability claims.

(3) TREATMENT OF STATES WITH ALTERNATIVE SYSTEM IN EFFECT.—If the alternative Federal ADR system established under this subsection is applied with respect to a State for a calendar year—

(A) the State shall reimburse the United States (at such time and in such manner as the Secretary may require) for the costs incurred by the United States during the year as a result of the application of the system with respect to the State; and

(B) notwithstanding any other provision of law, no funds may be paid to the State (or to any unit of local government in the State) or to any entity in the State under the Public Health Service Act.

SEC. 333. REPORTS ON IMPLEMENTATION AND EFFECTIVENESS OF ALTERNATIVE DISPUTE RESOLUTION SYSTEMS.

(a) IN GENERAL.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall prepare and submit to the Congress a report describing and evaluating State alternative dispute resolution systems operated pursuant to this subtitle and the alternative Federal system established under section 332(b).

(b) CONTENTS OF REPORT.—The Secretary shall include in the report prepared and submitted under subsection (a)—

(1) information on—

(A) the effect of the alternative dispute resolution systems on the cost of health care within each State;

(B) the impact of such systems on the access of individuals to health care within the State; and

(C) the effect of such systems on the quality of health care provided within the State; and

(2) to the extent that such report does not provide information on nofault systems operated by States as alternative dispute resolution systems pursuant to this subtitle, an analysis of the feasibility and desirability of establishing a system under which

medical malpractice liability claims shall be resolved on a no-fault basis.

TITLE IV—ANTITRUST PROVISIONS

SEC. 401. EXEMPTION FROM ANTITRUST LAWS FOR CERTAIN COMPETITIVE AND COLLABORATIVE ACTIVITIES.

(a) EXEMPTION DESCRIBED.—An activity relating to the provision of health care services shall be exempt from the antitrust laws if—

(1) the activity is within one of the categories of safe harbors described in section 402;

(2) the activity is within an additional safe harbor designated by the Attorney General under section 403; or

(3) the activity is specified in and in compliance with the terms of a certificate of review issued by the Attorney General under section 404 and the activity occurs—

(A) while the certificate is in effect; or

(B) in the case of a certificate issued during the 2-year period beginning on the date of the enactment of this Act, at any time on or after the first day of the 2-year period that ends on the date the certificate takes effect.

(b) AWARD OF ATTORNEY'S FEES AND COSTS OF SUIT.—

(1) IN GENERAL.—If any person brings an action alleging a claim under the antitrust laws and the activity on which the claim is based is found by the court to be exempt from such laws under subsection (a), the court shall, at the conclusion of the action—

(A) award to a substantially prevailing claimant the cost of suit attributable to such claim, including a reasonable attorney's fee; or

(B) award to a substantially prevailing party defending against such claim the cost of such suit attributable to such claim, including reasonable attorney's fee, if the claim, or the claimant's conduct during litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith.

(2) OFFSET IN CASES OF BAD FAITH.—The court may reduce an award made pursuant to paragraph (1) in whole or in part by an award in favor of another party for any part of the cost of suit (including a reasonable attorney's fee) attributable to conduct during the litigation by any prevailing party

that the court finds to be frivolous, unreasonable, without foundation, or in bad faith.

SEC. 402. SAFE HARBORS.

The following activities are safe harbors for purposes of section 401(a)(1):

(1) COMBINATIONS WITH MARKET SHARE BELOW THRESHOLD.—Activities relating to health care services of any combination of health care providers if the number of each type or specialty of provider in question does not exceed 20 percent of the total number of such type or specialty of provider in the relevant market area.

(2) ACTIVITIES OF MEDICAL SELF-REGULATORY ENTITIES.—

(A) IN GENERAL.—Subject to subparagraph (B), any activity of a medical self-regulatory entity relating to standard setting or standard enforcement activities that are designed to promote the quality of health care provided to patients.

(B) EXCEPTION.—No activity of a medical self-regulatory entity may be deemed to fall under the safe harbor established under this paragraph if the activity is conducted for purposes of financial gain.

(3) PARTICIPATION IN SURVEYS.—The participation of a provider of health care services in a written survey of the prices of services, reimbursement levels, or the compensation and benefits of employees and personnel, but only if—

(A) the survey is conducted by a third party, such as a purchaser of health care services, governmental entity, institution of higher education, or trade association;

(B) the information provided by participants in the survey is based on prices charged, reimbursements received, or compensation and benefits paid prior to the third month preceding the month in which the information is provided; and

(C) the results of the survey are disseminated, the results are aggregated in a manner that ensures that no recipient of the results may identify the prices charged, reimbursement received, or compensation and benefits paid by any particular provider.

(4) JOINT VENTURES FOR HIGH TECHNOLOGY AND COSTLY EQUIPMENT AND SERVICES.—Any activity of a health care cooperative venture relating to the purchase, operation, or marketing of high tech-

nology or other expensive medical equipment, or the provision of high cost or complex services, but only if the number of participants in the venture does not exceed the lowest number needed to support the venture. Other providers may be included in the venture, but only if such other providers could not purchase, operate, or market such equipment or provide a competing service either alone or through the formation of a competing venture.

(5) HOSPITAL MERGERS.—Activities relating to a merger of 2 hospitals if, during the 3-year period preceding the merger, one of the hospitals had an average of 200 or fewer operational beds and an average daily inpatient census of less than 60 percent of such beds.

(6) JOINT PURCHASING ARRANGEMENTS.—Any joint purchasing arrangement among health care providers if—

(A) the purchases under the arrangement represent less than 35 percent of the total sales of the product or service purchased in the relevant market; and

(B) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or

services sold by each participant in the joint purchasing arrangement.

(7) NEGOTIATIONS.—Activities consisting of good faith negotiations to carry out any activity—

(A) described in this section;

(B) within an additional safe harbor designated by the Attorney General under section 403;

(C) that is the subject of an application for a certificate of review under section 404; or

(D) that is deemed a submission of a notification under section 405(a)(2)(B), without regard to whether such an activity is carried out.

SEC. 403. DESIGNATION OF ADDITIONAL SAFE HARBORS.

(a) IN GENERAL.—

(1) SOLICITATION OF PROPOSALS.—Not later than 30 days after the date of the enactment of this Act, the Attorney General shall publish a notice in the Federal Register soliciting proposals for additional safe harbors.

(2) REVIEW AND REPORT ON PROPOSED SAFE HARBORS.—Not later than 180 days after the date of the enactment of this Act, the Attorney General (in consultation with the Secretary and the Chair shall—

(A) review the proposed safe harbors submitted under paragraph (1); and

(B) submit a report to Congress describing the proposals to be included in the publication of additional safe harbors described in paragraph (3) and the proposals that are not to be so included, together with explanations therefore.

(3) PUBLICATION OF ADDITIONAL SAFE HARBORS.—Not later than 180 days after the date of the enactment of this Act, the Attorney General (in consultation with the Secretary and the Chair shall publish in the Federal Register proposed additional safe harbors for purposes of section 401(a)(2) for providers of health care services. Not later than 180 days after publishing such proposed safe harbors in the Federal Register, the Attorney General shall issue final rules establishing such safe harbors.

(b) CRITERIA FOR SAFE HARBORS.—In establishing safe harbors under subsection (a), the Attorney General shall take into account the following:

(1) The extent to which a competitive or collaborative activity will accomplish any of the following:

(A) An increase in access to health care services.

(B) The enhancement of the quality of health care services.

(C) The establishment of cost efficiencies that will be passed on to consumers, including economies of scale and reduced transaction and administrative costs.

(D) An increase in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

(E) An improvement in the utilization of health care resources or the reduction in the inefficient duplication of the use of such resources.

(2) Whether the designation of an activity as a safe harbor under subsection (a) will result in the following outcomes:

(A) Health plans and other health care insurers, consumers of health care services, and health care providers will be better able to negotiate payment and service arrangements which will reduce costs to consumers.

(B) Taking into consideration the characteristics of the particular purchasers and providers involved, competition will not be unduly restricted.

(C) Equally efficient and less restrictive alternatives do not exist to meet the criteria described in paragraph (1).

(D) The activity will not unreasonably foreclose competition by denying competitors a necessary element of competition.

SEC. 404. CERTIFICATES OF REVIEW.

(a) ESTABLISHMENT OF PROGRAM.—In consultation with the Secretary and the Chair, the Attorney General shall (not later than 180 days after the date of the enactment of this Act) issue certificates of review in accordance with this section for providers of health care services and advise and assist any person with respect to applying for such a certificate of review.

(b) PROCEDURES FOR APPLICATION FOR CERTIFICATE.—

(1) FORM; CONTENT.—To apply for a certificate of review, a person shall submit to the Attorney General a written application which—

(A) specifies the activities relating to the provision of health care services which satisfy

the criteria described in section 403(b) and which will be included in the certificate; and

(B) is in a form and contains any information, including information pertaining to the overall market in which the applicant operates, required by rule or regulation promulgated under section 407.

(2) PUBLICATION OF NOTICE IN FEDERAL REGISTER.—Not later than 10 days after an application submitted under paragraph (1) is received by the Attorney General, the Attorney General shall publish in the Federal Register a notice that announces that an application for a certificate of review has been submitted, identifies each person submitting the application, and describes the conduct for which the application is submitted.

(3) ESTABLISHMENT OF PROCEDURES FOR ISSUANCE OF CERTIFICATE.—In consultation with the Chair and the Secretary, the Attorney General shall establish procedures to be used in applying for and in determining whether to approve an application for a certificate of review under this title. Under such procedures the Attorney General shall approve an application if the Attorney General determines that the activities to be covered under the certificate will

satisfy the criteria described in section 403(b) for additional safe harbors designated under such section and that the benefits of the issuance of the certificate will outweigh any disadvantages that may result from reduced competition.

(4) TIMING FOR DECISION ON APPLICATION.—

(A) IN GENERAL.—Not later than 90 days after the Attorney General receives an application for a certificate of review, the Attorney General shall determine whether the applicant's health care market activities are in accordance with the procedures described in paragraph (3). If the Attorney General, with the concurrence of the Secretary, determines that such procedures are met, the Attorney General shall issue to the applicant a certificate of review. The certificate of review shall specify—

(i) the health care market activities to which the certificate applies;

(ii) the person to whom the certificate of review is issued; and

(iii) any terms and conditions the Attorney General or the Secretary deems necessary to assure compliance with the appli-

cable procedures described in paragraph (3).

(B) APPLICATIONS DEEMED APPROVED.—If the Attorney General does not reject an application before the expiration of the 90-day period beginning on the date the Attorney General receives the application, the Attorney General shall be deemed to have approved the application and to have issued a certificate of review relating to the applicant's health care market activities covered under the application.

(5) EXPEDITED ACTION.—If the applicant indicates a special need for prompt disposition, the Attorney General and the Secretary may expedite action on the application, except that no certificate of review may be issued within 30 days of publication of notice in the Federal Register under subsection (b)(2).

(6) ACTIONS UPON DENIAL.—

(A) NOTIFICATION.—If the Attorney General denies in whole or in part an application for a certificate, the Attorney General shall notify the applicant of the Attorney General's determination and the reasons for it.

(B) REQUEST FOR RECONSIDERATION.—An applicant may, within 30 days of receipt of notification that the application has been denied in whole or in part, request the Attorney General to reconsider the determination. The Attorney General, with the concurrence of the Secretary, shall notify the applicant of the determination upon reconsideration within 30 days of receipt of the request.

(C) RETURN OF DOCUMENTS.—If the Attorney General denies an application for the issuance of a certificate of review and thereafter receives from the applicant a request for the return of documents submitted by the applicant in connection with the application for the certificate, the Attorney General and the Secretary shall return to the applicant, not later than 30 days after receipt of the request, the documents and all copies of the documents available to the Attorney General and the Secretary, except to the extent that the information has been made public under an exception to the rule against public disclosure described in subsection (g)(2)(B).

(7) FRAUDULENT PROCUREMENT.—A certificate of review shall be void ab initio with respect to any health care market activities for which the certificate was procured by fraud.

(c) AMENDMENT AND REVOCATION OF CERTIFICATES.—

(1) NOTIFICATION OF CHANGES.—Any applicant who receives a certificate of review—

(A) shall promptly report to the Attorney General any change relevant to the matters specified in the certificate; and

(B) may submit to the Attorney General an application to amend the certificate to reflect the effect of the change on the conduct specified in the certificate.

(2) AMENDMENT TO CERTIFICATE.—An application for an amendment to a certificate of review shall be treated as an application for the issuance of a certificate. The effective date of an amendment shall be the date on which the application for the amendment is submitted to the Attorney General.

(3) REVOCATION.—

(A) GROUNDS FOR REVOCATION.—In accordance with this paragraph, the Attorney General may revoke in whole or in part a cer-

tificate of review issued under this section. The following shall be considered grounds for the revocation of a certificate:

(i) After the expiration of the 2-year period beginning on the date a person's certificate is issued, the activities of the person have not substantially accomplished the purposes for the issuance of the certificate.

(ii) The person has failed to comply with any of the terms or conditions imposed under the certificate by the Attorney General or the Secretary under subsection (b)(4).

(iii) The activities covered under the certificate no longer satisfy the criteria set forth in section 403(b).

(B) REQUEST FOR COMPLIANCE INFORMATION.—If the Attorney General or Secretary has reason to believe that any of the grounds for revocation of a certificate of review described in subparagraph (A) may apply to a person holding the certificate, the Attorney General shall request such information from such person as the Attorney General or the Sec-

retary deems necessary to resolve the matter of compliance. Failure to comply with such request shall be grounds for revocation of the certificate under this paragraph.

(C) PROCEDURES FOR REVOCATION.—If the Attorney General or the Secretary determines that any of the grounds for revocation of a certificate of review described in subparagraph (A) apply to a person holding the certificate, or that such person has failed to comply with a request made under subparagraph (B), the Attorney General shall give written notice of the determination to such person. The notice shall include a statement of the circumstances underlying, and the reasons in support of, the determination. In the 60-day period beginning 30 days after the notice is given, the Attorney General shall revoke the certificate or modify it as the Attorney General or the Secretary deems necessary to cause the certificate to apply only to activities that meet the procedures for the issuance of certificates described in subsection (b)(2).

(D) INVESTIGATION AUTHORITY.—For purposes of carrying out this paragraph, the

Attorney General may conduct investigations in the same manner as the Attorney General conducts investigations under section 3 of the Antitrust Civil Process Act, except that no civil investigative demand may be issued to a person to whom a certificate of review is issued if such person is the target of such investigation.

(d) REVIEW OF DETERMINATIONS.—

(1) AVAILABILITY OF REVIEW FOR CERTAIN ACTIONS.—If the Attorney General denies, in whole or in part, an application for a certificate of review or for an amendment to a certificate, or revokes or modifies a certificate pursuant to paragraph (3), the applicant or certificate holder (as the case may be) may, within 30 days of the denial or revocation, bring an action in any appropriate district court of the United States to set aside the determination on the ground that such determination is erroneous based on the preponderance of the evidence.

(2) NO OTHER REVIEW PERMITTED.—Except as provided in paragraph (1), no action by the Attorney General or the Secretary pursuant to this title shall be subject to judicial review.

(3) EFFECT OF REJECTED APPLICATION.—If the Attorney General denies, in whole or in part, an

application for a certificate of review or for an amendment to a certificate, or revokes or amends a certificate, neither the negative determination nor the statement of reasons therefore shall be admissible in evidence, in any administrative or judicial proceeding, concerning any claim under the antitrust laws.

(e) PUBLICATION OF DECISIONS.—The Attorney General shall publish a notice in the Federal Register on a timely basis of each decision made with respect to an application for a certificate of review under this section or the amendment or revocation of such a certificate, in a manner that protects the confidentiality of any proprietary information relating to the application.

(f) ANNUAL REPORTS.—Every person to whom a certificate of review is issued shall submit to the Attorney General an annual report, in such form and at such time as the Attorney General may require, that contains any necessary updates to the information required under subsection (b) and a description of the activities of the holder under the certificate during the preceding year.

(g) RESTRICTIONS ON DISCLOSURE OF INFORMATION.—

(1) WAIVER OF DISCLOSURE REQUIREMENTS UNDER ADMINISTRATIVE PROCEDURE ACT.—Infor-

mation submitted by any person in connection with the issuance, amendment, or revocation of a certificate of review shall be exempt from disclosure under section 552 of title 5, United States Code.

(2) RESTRICTIONS ON DISCLOSURE OF COMMERCIAL OR FINANCIAL INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), no officer or employee of the United States shall disclose commercial or financial information submitted in connection with the issuance, amendment, or revocation of a certificate of review if the information is privileged or confidential and if disclosure of the information would cause harm to the person who submitted the information.

(B) EXCEPTIONS.—Subparagraph (A) shall not apply with respect to information disclosed—

(i) upon a request made by the Congress or any committee of the Congress;

(ii) in a judicial or administrative proceeding, subject to appropriate protective orders;

(iii) with the consent of the person who submitted the information;

(iv) in the course of making a determination with respect to the issuance, amendment, or revocation of a certificate of review, if the Attorney General deems disclosure of the information to be necessary in connection with making the determination;

(v) in accordance with any requirement imposed by a statute of the United States; or

(vi) in accordance with any rule or regulation promulgated to permit the disclosure of the information to an agency of the United States or of a State on the condition that the agency will disclose the information only under the circumstances specified in clauses (i) through (v).

(3) PROHIBITION AGAINST USE OF INFORMATION TO SUPPORT OR ANSWER CLAIMS UNDER ANTITRUST LAWS.—Any information disclosed in an application for a certificate of review under this section shall only be admissible into evidence in a judicial or administrative proceeding for the sole purpose of establishing that a person is entitled to the protections provided by such a certificate.

SEC. 405. NOTIFICATIONS PROVIDING REDUCTION IN CERTAIN PENALTIES UNDER ANTITRUST LAW FOR HEALTH CARE COOPERATIVE VENTURES.

(a) NOTIFICATIONS DESCRIBED.—

(1) SUBMISSION OF NOTIFICATION BY VENTURE.—Any party to a health care cooperative venture, acting on such venture's behalf, may, not later than 90 days after entering into a written agreement to form such venture or not later than 90 days after the date of the enactment of this Act, whichever is later, file with the Attorney General a written notification disclosing—

(A) the identities of the parties to such venture;

(B) the nature and objectives of such venture; and

(C) such additional information as the Attorney General may require by regulation.

(2) ACTIVITIES DEEMED SUBMISSION OF NOTIFICATION.—The following health care cooperative ventures shall be deemed to have filed a written notification with respect to the venture under paragraph (1):

(A) SUBMISSION OF APPLICATION FOR CERTIFICATE OF REVIEW.—Any health care co-

operative venture for which an application for a certificate of review is filed with the Attorney General under section 403.

(B) CERTAIN VENTURES.—Any health care cooperative venture meeting the following requirements:

(i) The venture consists of a network of noninstitutional providers not greater than—

(I) in the case of a nonexclusive network in which the participating members are permitted to create or join other competing networks, 50 percent of the providers of health care services in the relevant geographic area and 50 percent of the members of the provider specialty group in the relevant market; or

(II) in the case of an exclusive network in which the participating members are not permitted to create or join other competing networks, 35 percent of the providers of health care services in the relevant geographic area and 35 percent of the members

of the provider specialty group in the relevant market.

(ii) Each member of the venture assumes substantial financial risk for the operation of the venture through risk-sharing arrangements, including (but not limited to)—

(I) the acceptance of capitation contracts;

(II) the acceptance of contracts with fee withholding mechanisms relating to the ability to meet established goals for utilization review and management; and

(III) the holding by members of significant ownership or equity interests in the venture, where the capital contributed by the members is used to fund the operational costs of the venture such as administration, marketing, and computer-operated medical information, if the venture develops and operates comprehensive programs for utilization management and quality assurance that include controls

over the use of institutional, specialized, and ancillary medical services.

(3) SUBMISSION OF ADDITIONAL INFORMATION.—

(A) REQUEST OF ATTORNEY GENERAL.—At any time after receiving a notification filed under paragraph (1), the Attorney General may require the submission of additional information or documentary material relevant to the proposed health care cooperative venture.

(B) PARTIES TO VENTURE.—Any party to a health care cooperative venture may submit such additional information on the venture's behalf as may be appropriate to ensure that the venture will receive the protections provided under subsection (b).

(C) REQUIRED SUBMISSION OF INFORMATION ON CHANGES TO VENTURE.—A health care cooperative venture for which a notification is in effect under this section shall submit information on any change in the membership of the venture not later than 90 days after such change occurs.

(4) PUBLICATION OF NOTIFICATION.—

(A) INFORMATION MADE PUBLICLY AVAILABLE.—Not later than 30 days after receiving a notification with respect to a venture under paragraph (1), the Attorney General shall publish in the Federal Register a notice with respect to the venture that identifies the parties to the venture and generally describes the purpose and planned activity of the venture. Prior to its publication, the contents of the notice shall be made available to the parties to the venture.

(B) RESTRICTION ON DISCLOSURE OF OTHER INFORMATION.—All information and documentary material submitted pursuant to this section and all information obtained by the Attorney General in the course of any investigation or case with respect to a potential violation of the antitrust laws by the health care cooperative venture (other than information and material described in subparagraph (A)) shall be exempt from disclosure under section 552 of title 5, United States Code, and shall not be made publicly available by any agency of the United States to which such section applies except in

a judicial proceeding in which such information and material is subject to any protective order.

(5) WITHDRAWAL OF NOTIFICATION.—Any person who files a notification pursuant to this section may withdraw such notification before a publication by the Attorney General pursuant to paragraph (4). Any person who is deemed to have filed a notification under paragraph (2)(A) shall be deemed to have withdrawn the notification if the certificate of review in question is revoked or withdrawn under section 404.

(6) NO JUDICIAL REVIEW PERMITTED.—Any action taken or not taken by the Attorney General with respect to notifications filed pursuant to this subsection shall not be subject to judicial review.

(b) PROTECTIONS FOR VENTURES SUBJECT TO NOTIFICATION.—

(1) IN GENERAL.—

(A) PROTECTIONS DESCRIBED.—The provisions of paragraphs (2), (3), (4), and (5) shall apply with respect to any action under the antitrust laws challenging conduct within the scope of a notification which is in effect pursuant to subsection (a)(1).

(B) TIMING OF PROTECTIONS.—The protections described in this subsection shall apply to the venture that is the subject of a notification under subsection (a)(1) as of the earlier of—

(i) the date of the publication in the Federal Register of the notice published with respect to the notification; or

(ii) if such notice is not published during the period required under subsection (a)(4), the expiration of the 30-day period that begins on the date the Attorney General receives any necessary information required to be submitted under subsection (a)(1) or any additional information required by the Attorney General under subsection (a)(3)(A).

(2) APPLICABILITY OF RULE OF REASON STANDARD.—In any action under the antitrust laws, the conduct of any person which is within the scope of a notification filed under subsection (a) shall not be deemed illegal per se, but shall be judged on the basis of its reasonableness, taking into account all relevant factors affecting competition, including, but

not limited to, effects on competition in relevant markets.

(3) LIMITATION ON RECOVERY TO ACTUAL DAMAGES AND INTEREST.—Notwithstanding section 4 of the Clayton Act, any person who is entitled to recovery under the antitrust laws for conduct that is within the scope of a notification filed under subsection (a) shall recover the actual damages sustained by such person and interest calculated at the rate specified in section 1961 of title 28, United States Code, for the period beginning on the earliest date for which injury can be established and ending on the date of judgment, unless the court finds that the award of all or part of such interest is unjust under the circumstances.

(4) AWARD OF ATTORNEY'S FEES AND COSTS OF SUIT.—

(A) IN GENERAL.—In any action under the antitrust laws brought against a health care co-operative venture for conduct that is within the scope of a notification filed under subsection (a), the court shall, at the conclusion of the action—

(i) award to a substantially prevailing claimant the cost of suit attributable to

such claim, including a reasonable attorney's fee, or

(ii) award to a substantially prevailing party defending against such claim the cost of such suit attributable to such claim, including reasonable attorney's fee, if the claim, or the claimant's conduct during litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith.

(B) OFFSET IN CASES OF BAD FAITH.—The court may reduce an award made pursuant to subparagraph (A) in whole or in part by an award in favor of another party for any part of the cost of suit (including a reasonable attorney's fee) attributable to conduct during the litigation by any prevailing party that the court finds to be frivolous, unreasonable, without foundation, or in bad faith.

(5) RESTRICTIONS ON ADMISSIBILITY OF INFORMATION.—

(A) IN GENERAL.—Any information disclosed in a notification submitted under subsection (a)(1) and the fact of the publication of a notification by the Attorney General under

subsection (a)(4) shall only be admissible into evidence in a judicial or administrative proceeding for the sole purpose of establishing that a party to a health care cooperative venture is entitled to the protections described in this subsection.

(B) ACTIONS OF ATTORNEY GENERAL.—No action taken by the Attorney General pursuant to this section shall be admissible into evidence in any judicial or administrative proceeding for the purpose of supporting or answering any claim under the antitrust laws.

SEC. 406. REVIEW AND REPORTS ON SAFE HARBORS AND CERTIFICATES OF REVIEW.

(a) IN GENERAL.—The Attorney General (in consultation with the Secretary and the Chair) shall periodically review the safe harbors described in section 402, the additional safe harbors designated under section 403, and the certificates of review issued under section 404, and—

(1) with respect to the safe harbors described in section 402, submit such recommendations to Congress as the Attorney General considers appropriate for modifications of such safe harbors;

(2) with respect to the additional safe harbors designated under section 403, issue proposed revi-

sions to such activities and publish the revisions in the Federal Register; and

(3) with respect to the certificates of review, submit a report to Congress on the issuance of such certificates, and shall include in the report a description of the effect of such certificates on increasing access to high quality health care services at reduced costs.

(b) RECOMMENDATIONS FOR LEGISLATION.—The Attorney General shall include in the reports submitted under subsection (a)(3) any recommendations of the Attorney General for legislation to improve the program for the issuance of certificates of review established under this title.

SEC. 407. RULES, REGULATIONS, AND GUIDELINES.

(a) SAFE HARBORS, CERTIFICATES, AND NOTIFICATIONS.—The Attorney General, with the concurrence of the Secretary, shall promulgate such rules, regulations, and guidelines as are necessary to carry out sections 402, 403, 404, and 405, including guidelines defining or relating to relevant geographic and product markets for health care services and providers of health care services.

(b) GUIDANCE FOR PROVIDERS.—

(1) IN GENERAL.—To promote greater certainty regarding the application of the antitrust laws

to activities in the health care market, the Attorney General, in consultation with the Secretary and the Chair, shall (not later than 1 year after the date of the enactment of this Act), taking into account the criteria used to designate additional safe harbors under section 403 and grant certificates of review under section 404, publish guidelines—

(A) to assist providers of health care services in analyzing whether the activities of such providers may be subject to a safe harbor under section 402 or 403; and

(B) describing specific types of activities which would meet the requirements for a certificate of review under section 404, and summarizing the factual and legal bases on which the activities would meet the requirements.

(2) PERIODIC UPDATE.—The Attorney General shall periodically update the guidelines published under paragraph (1) as the Attorney General considers appropriate.

(3) WAIVER OF ADMINISTRATIVE PROCEDURE ACT.—Section 553 of title 5, United States Code, shall not apply to the issuance of guidelines under paragraph (1).

SEC. 408. ESTABLISHMENT OF HHS OFFICE OF HEALTH CARE COMPETITION POLICY.

(a) IN GENERAL.—There is established within the Department of Health and Human Services an Office to be known as the Office of Health Care Competition Policy (hereafter in this section referred to as the ''Office''). The Office shall be headed by a director, who shall be appointed by the Secretary.

(b) DUTIES.—The Office shall coordinate the responsibilities of the Secretary under this Act and otherwise assist the Secretary in developing policies relating to the competitive and collaborative activities of providers of health care services.

SEC. 409. DEFINITIONS.

As used in this Act:

(1) ANTITRUST LAWS.—The term ''antitrust laws''—

(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section applies to unfair methods of competition; and

(B) includes any State law similar to the laws referred to in subparagraph (A).

(2) CHAIR.—The term ''Chair'' means the Chair of the Federal Trade Commission.

(3) HEALTH BENEFIT PLAN.—The term ''health benefit plan'' means any hospital or medical expense incurred policy or certificate, hospital or medical service plan contract, or health maintenance subscriber contract, or a multiple employer welfare arrangement or employee benefit plan (as defined under the Employee Retirement Income Security Act of 1974) which provides benefits with respect to health care services.

(4) HEALTH CARE COOPERATIVE VENTURE.—The term ''health care cooperative venture'' means any activities, including attempts to enter into or perform a contract or agreement, carried out by 2 or more persons for the purpose of providing health care services.

(5) HEALTH CARE SERVICES.—The term ''health care services'' means any services for which payment may be made under a health benefit plan, including services related to the delivery or administration of such services.

(6) MEDICAL SELF-REGULATORY ENTITY.—The term ''medical self-regulatory entity'' means a medical society or association, a specialty board, a recog-

nized accrediting agency, or a hospital medical staff, and includes the members, officers, employees, consultants, and volunteers or committees of such an entity.

(7) PERSON.—The term ''person'' includes a State or unit of local government.

(8) PROVIDER OF HEALTH CARE SERVICES.—The term ''provider of health care services'' means any individual or entity that is engaged in the delivery of health care services in a State and that is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State.

(9) SPECIALTY GROUP.—The term ''specialty group'' means a medical specialty or subspecialty in which a provider of health care services may be licensed to practice by a State (as determined by the Secretary in consultation with the certification boards for such specialties and subspecialties).

(10) The term ''standard setting and enforcement activities'' means—

(A) accreditation of health care practitioners, health care providers, medical education institutions, or medical education programs,

(B) technology assessment and risk management activities,

(C) the development and implementation of practice guidelines or practice parameters, or

(D) official peer review proceedings undertaken by a hospital medical staff (or committee thereof) or a medical society or association for purposes of evaluating the professional conduct or quality of health care provided by a medical professional.

TITLE V—ANTI-FRAUD AND ABUSE CONTROL PROGRAM

Subtitle A—All-Payer Fraud and Abuse Control Program

SEC. 501. ALL-PAYER FRAUD AND ABUSE CONTROL PROGRAM.

(a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—Not later than January 1, 1995, the Secretary shall establish in the Office of the Inspector General of the Department of Health and Human Services a program (hereafter referred to in this section as the ''program'')—

(A) to coordinate Federal, State, and local law enforcement programs to control fraud and

abuse with respect to the delivery of and payment for health care in the United States,

(B) to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States, and

(C) to facilitate the enforcement of the provisions of sections 1128, 1128A, and 1128B of the Social Security Act and other statutes applicable to health care fraud and abuse.

(2) COORDINATION WITH HEALTH CARE PLANS.—In carrying out the program established under paragraph (1), the Secretary shall consult with, and arrange for the sharing of data with, representatives of health care plans.

(3) REGULATIONS.—

(A) IN GENERAL.—The Secretary shall by regulation establish standards to carry out the program under paragraph (1).

(B) INFORMATION STANDARDS.—

(i) IN GENERAL.—Standards under subparagraph (A) shall include standards relating to the furnishing of information by health care plans, providers, and others to enable the Secretary to carry out the pro-

gram (including coordination with health care plans under paragraph (2)).

(ii) CONFIDENTIALITY.—Standards under subparagraph (A) shall include procedures to assure that such information is provided and utilized in a manner that appropriately protects the confidentiality of the information and the privacy of individuals receiving health care services and items.

(iii) QUALIFIED IMMUNITY FOR PROVIDING INFORMATION.—The provisions of section 1157(a) of the Social Security Act (relating to limitation on liability) shall apply to a person providing information to the Secretary under the program under this section, with respect to the Secretary's performance of duties under the program, in the same manner as such section applies to information provided to organizations with a contract under part B of title XI of such Act, with respect to the performance of such a contract.

(C) DISCLOSURE OF OWNERSHIP INFORMATION.—

(i) IN GENERAL.—Standards under subparagraph (A) shall include standards relating to the disclosure of ownership information described in clause (ii) by any entity providing health care services and items.

(ii) OWNERSHIP INFORMATION DESCRIBED.—The ownership information described in this clause includes—

(I) a description of such items and services provided by such entity;

(II) the names and unique physician identification numbers of all physicians with a financial relationship (as defined in section 1877(a)(2) of the Social Security Act) with such entity;

(III) the names of all other individuals with such an ownership or investment interest in such entity; and

(IV) any other ownership and related information required to be disclosed by such entity under section 1124 or section 1124A of the Social Security Act.

(4) AUTHORIZATION OF APPROPRIATIONS FOR INVESTIGATIONS AND OTHER PERSONNEL.—In addition to any other amounts authorized to be appropriated to the Secretary for health care anti-fraud and abuse activities for a fiscal year, there are authorized to be appropriated additional amounts as may be necessary to enable the Secretary to conduct investigations and audits of allegations of health care fraud and abuse and otherwise carry out the program established under paragraph (1) in a fiscal year.

(5) ENSURING ACCESS TO DOCUMENTATION.—

(A) IN GENERAL.—The Inspector General of the Department of Health and Human Services is authorized to exercise the authority described in paragraphs (4) and (5) of section 6 of the Inspector General Act of 1978 (relating to subpoenas and administration of oaths) with respect to the activities under the program established under this subsection to the same extent as such Inspector General may exercise such authorities to perform the functions assigned by such Act.

(B) PERMISSIVE EXCLUSION.—Section 1128(b) of the Social Security Act (42 U.(b))

is amended by adding at the end the following new paragraph:

''(15) FAILURE TO SUPPLY REQUESTED INFORMATION TO THE INSPECTOR GENERAL.—Any individual or entity that fails fully and accurately to provide, upon request of the Inspector General of the Department of Health and Human Services, records, documents, and other information necessary for the purposes of carrying out activities under the all-payer fraud and abuse control program established under section 501 of the Advancement of Health Care Reform Act of 1994.''.

(6) HEALTH CARE PLAN DEFINED.—For the purposes of this subsection, the term ''health care plan'' shall have the meaning given such term in section 1128(i) of the Social Security Act.

(b) ESTABLISHMENT OF ANTI-FRAUD AND ABUSE TRUST FUND.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—There is hereby created on the books of the Treasury of the United States a trust fund to be known as the ''Anti-Fraud and Abuse Trust Fund'' (hereafter referred to as the ''Trust Fund''). The Trust Fund shall consist of such gifts and bequests as

may be made as provided in subparagraph (B) and such amounts as may be deposited in, or appropriated to, such Trust Fund as provided in subsection (a)(5), and title XI of the Social Security Act.

(B) AUTHORIZATION TO ACCEPT GIFTS.—The Managing Trustee of the Trust Fund is authorized to accept on behalf of the United States money gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Trust Fund, or any activity financed through the Trust Fund.

(2) MANAGEMENT.—

(A) IN GENERAL.—The Trust Fund shall be managed by the Secretary through a Managing Trustee designated by the Secretary.

(B) INVESTMENT OF FUNDS.—

(i) IN GENERAL.—It shall be the duty of the Managing Trustee to invest such portion of the Trust Fund as is not, in the Managing Trustee's judgment, required to meet current withdrawals.

(ii) GENERAL FORM OF INVESTMENT.—Investments described in clause (i) may be made only in interest-bearing obli-

gations of the United States or in obligations guaranteed as to both principal and interest by the United States. For such purpose such obligations may be acquired—

(I) on original issue at the issue price, or

(II) by purchase of outstanding obligations at market price.

(iii) ISSUANCE OF PUBLIC-DEBT OBLIGATIONS.—The purposes for which obligations of the United States may be issued under chapter 31 of title 31, United States Code, are hereby extended to authorize the issuance at par of public-debt obligations for purchase by the Trust Fund. Such obligations issued for purchase by the Trust Fund shall have maturities fixed with due regard for the needs of the Trust Fund and shall bear interest at a rate equal to the average market yield (computed by the Managing Trustee on the basis of market quotations as of the end of the calendar month next preceding the date of such issue) on all marketable interest-bearing

obligations of the United States then forming a part of the public debt which are not due or callable until after the expiration of 4 years from the end of such calendar month, except that where such average is not a multiple of ⅛ of 1 percent, the rate of interest on such obligations shall be the multiple of ⅛ of 1 percent nearest such market yield.

(iv) PURCHASES OF OTHER OBLIGATIONS.—The Managing Trustee may purchase other interest-bearing obligations of the United States or obligations guaranteed as to both principal and interest by the United States, on original issue or at the market price, only where the Managing Trustee determines that the purchase of such other obligations is in the public interest.

(C) SALE OF OBLIGATIONS.—Any obligations acquired by the Trust Fund (except public-debt obligations issued exclusively to the Trust Fund) may be sold by the Managing Trustee at the market price, and such public-

debt obligations may be redeemed at par plus accrued interest.

(D) INTEREST ON OBLIGATIONS AND PROCEEDS FROM SALE OR REDEMPTION OF OBLIGATIONS.—The interest on, and the proceeds from the sale or redemption of, any obligations held in the Trust Fund shall be credited to and form a part of the Trust Fund.

(E) RECEIPTS AND DISBURSEMENTS NOT INCLUDED IN UNITED STATES GOVERNMENT BUDGET TOTALS.—The receipts and disbursements of the Secretary in the discharge of the functions of the Secretary under the all-payer fraud and abuse control program established under subsection (a) shall not be included in the totals of the budget of the United States Government. For purposes of part C of the Balanced Budget and Emergency Deficit Control Act of 1985, the Secretary and the Trust Fund shall be treated in the same manner as the Federal Retirement Thrift Investment Board and the Thrift Savings Fund, respectively. The United States is not liable for any obligation or liability incurred by the Trust Fund.

(3) USE OF FUNDS.—

(A) IN GENERAL.—Amounts in the Trust Fund shall be used without regard to fiscal year limitation to assist the Inspector General of the Department of Health and Human Services in carrying out the all-payer fraud and abuse control program established under subsection (a).

(B) OVERALL ADMINISTRATION.—The Managing Trustee shall also pay from time to time from the Trust Fund such amounts as the Secretary certifies are necessary to carry out the all-payer fraud and abuse control program established under subsection (a).

(4) ANNUAL REPORT.—The Managing Trustee shall be required to submit an annual report to Congress on the amount of revenue which is generated and disbursed by the Trust Fund in each fiscal year. Such report shall include an estimate of the amount of additional appropriations authorized under subsection (a)(5) necessary for the Secretary to conduct the all-payer fraud and abuse program established under subsection (a) in the next fiscal year.

SEC. 502. APPLICATION OF FEDERAL HEALTH ANTI-FRAUD AND ABUSE SANCTIONS TO ALL FRAUD AND ABUSE AGAINST ANY HEALTH CARE PLAN.

(a) CIVIL MONETARY PENALTIES.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended as follows:

(1) In subsection (a)(1), by inserting ''or of any health care plan (as defined in section 1128(i)),'' after ''subsection (i)(1)),''.

(2) In subsection (b)(1)(A), by inserting ''or under a health care plan'' after ''title XIX''.

(3) In subsection (f)—

(A) by redesignating paragraph (3) as paragraph (4); and

(B) by inserting after paragraph (2) the following new paragraph:

''(3) With respect to amounts recovered arising out of a claim under a health care plan, the portion of such amounts as is determined to have been paid by the plan shall be repaid to the plan, and the portion of such amounts attributable to the amounts recovered under this section by reason of the amendments made by title V of the Advancement of Health Care Reform Act of 1994 (as estimated by the Secretary) shall be deposited into the Anti-Fraud and

Abuse Trust Fund established under section 501(b) of such Act.''.

(4) In subsection (i)—

(A) in paragraph (2), by inserting ''or under a health care plan'' before the period at the end, and

(B) in paragraph (5), by inserting ''or under a health care plan'' after ''or XX''.

(b) CRIMES.—

(1) SOCIAL SECURITY ACT.—Section 1128B of such Act (42 U.S.C. 1320–7b) is amended as follows:

(A) In the heading, by adding at the end the following: ''OR HEALTH CARE PLANS''.

(B) In subsection (a)(1)—

(i) by striking ''title XVIII or'' and inserting ''title XVIII,'', and

(ii) by adding at the end the following: ''or a health care plan (as defined in section 1128(i)),''.

(C) In subsection (a)(5), by striking ''title XVIII or a State health care program'' and inserting ''title XVIII, a State health care program, or a health care plan''.

(D) In the second sentence of subsection (a)—

(i) by inserting after ''title XIX'' the following: ''or a health care plan'', and

(ii) by inserting after ''the State'' the following: ''or the plan''.

(E) In subsection (b)(1), by striking ''title XVIII or a State health care program'' each place it appears and inserting ''title XVIII, a State health care program, or a health care plan''.

(F) In subsection (b)(2), by striking ''title XVIII or a State health care program'' each place it appears and inserting ''title XVIII, a State health care program, or a health care plan''.

(G) In subsection (b)(3), by striking ''title XVIII or a State health care program'' each place it appears in subparagraphs (A) and (C) and inserting ''title XVIII, a State health care program, or a health care plan''.

(2) IDENTIFICATION OF COMMUNITY SERVICE OPPORTUNITIES.—Section 1128B of such Act (42 U.S.C. 1320a–7b) is further amended by adding at the end the following new subsection:

''(f) The Secretary may—

''(1) in consultation with State and local health care officials, identify opportunities for the satisfaction of community service obligations that a court may impose upon the conviction of an offense under this section, and

''(2) make information concerning such opportunities available to Federal and State law enforcement officers and State and local health care officials.''.

(c) HEALTH CARE PLAN DEFINED.—Section 1128 of such Act (42 U.S.C. 1320a–7) is amended by redesignating subsection (i) as subsection (j) and by inserting after subsection (h) the following new subsection:

''(i) HEALTH CARE PLAN DEFINED.—For purposes of sections 1128A and 1128B, the term 'health care plan' means a public or private program for the delivery of or payment for health care items or services other than the medicare program, the medicaid program, or a State health care program.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 1995.

SEC. 503. REPORTING OF FRAUDULENT ACTIONS UNDER MEDICARE.

Not later than 1 year after the date of the enactment of this Act, the Secretary shall establish a program through which individuals entitled to benefits under the medicare program may report to the Secretary on a confidential basis (at the individual's request) instances of suspected fraudulent actions arising under the program by providers of items and services under the program.

Subtitle B—Revisions to Current Sanctions for Fraud and Abuse

SEC. 511. MANDATORY EXCLUSION FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS.

(a) INDIVIDUAL CONVICTED OF FELONY RELATED TO FRAUD.—

(1) IN GENERAL.—Section 1128(a) of the Social Security Act (42 U.S.C. 1320a–7(a)) is amended by adding at the end the following new paragraph:

''(3) FELONY CONVICTION RELATING TO FRAUD.—Any individual or entity that has been convicted, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a program (other than those specifically described in paragraph

(1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.''.

(2) CONFORMING AMENDMENT.—Section 1128(b)(1) of such Act (42 U.S.C. 1320a–7(b)(1)) is amended—

(A) in the heading, by striking ''CONVICTION'' and inserting ''MISDEMEANOR CONVICTION''; and

(B) by striking ''criminal offense'' and inserting ''criminal offense consisting of a misdemeanor''.

(b) INDIVIDUAL CONVICTED OF FELONY RELATING TO CONTROLLED SUBSTANCE.—

(1) IN GENERAL.—Section 1128(a) of the Social Security Act (42 U.S.C. 1320a–7(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

''(4) FELONY CONVICTION RELATING TO CONTROLLED SUBSTANCE.—Any individual or entity that has been convicted, under Federal or State law, of a criminal offense consisting of a felony relating

to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.''.

(2) CONFORMING AMENDMENT.—Section 1128(b)(3) of such Act (42 U.S.C. 1320a–7(b)(3)) is amended—

(A) in the heading, by striking ''CONVICTION'' and inserting ''MISDEMEANOR CONVICTION''; and

(B) by striking ''criminal offense'' and inserting ''criminal offense consisting of a misdemeanor''.

SEC. 512. ESTABLISHMENT OF MINIMUM PERIOD OF EXCLUSION FOR CERTAIN INDIVIDUALS AND ENTITIES SUBJECT TO PERMISSIVE EXCLUSION FROM MEDICARE AND STATE HEALTH CARE PROGRAMS.

Section 1128(c)(3) of the Social Security Act (42 U.S.C. 1320a–7(c)(3)) is amended by adding at the end the following new subparagraphs:

''(D) In the case of an exclusion of an individual or entity under paragraph (1), (2), or (3) of subsection (b), the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of miti-

gating circumstances or that a longer period is appropriate because of aggravating circumstances.

''(E) In the case of an exclusion of an individual or entity under subsection (b)(4) or (b)(5), the period of the exclusion shall not be less than the period during which the individual's or entity's license to provide health care is revoked, suspended, or surrendered, or the individual or the entity is excluded or suspended from a Federal or State health care program.

''(F) In the case of an exclusion of an individual or entity under subsection (b)(6)(B), the period of the exclusion shall be not less than 1 year.''.

SEC. 513. PERMISSIVE EXCLUSION OF INDIVIDUALS WITH OWNERSHIP OR CONTROL INTEREST IN SANCTIONED ENTITIES.

Section 1128(b) of the Social Security Act (42 U.S.C. 1320a–7(b)), as amended by section 501(a)(5)(B), is further amended by adding at the end the following new paragraph:

''(16) INDIVIDUALS CONTROLLING A SANCTIONED ENTITY.—Any individual who has a direct or indirect ownership or control interest of 5 percent or more, or an ownership or control interest (as defined in section 1124(a)(3)) in, or who is an officer,

director, agent, or managing employee (as defined in section 1126(b)) of, an entity—

''(A) that has been convicted of any offense described in subsection (a) or in paragraph (1), (2), or (3) of this subsection;

''(B) against which a civil monetary penalty has been assessed under section 1128A; or

''(C) that has been excluded from participation under a program under title XVIII or under a State health care program.''.

SEC. 514. CIVIL MONETARY PENALTIES.

(a) PROHIBITION AGAINST OFFERING INDUCEMENTS TO INDIVIDUALS ENROLLED UNDER OR EMPLOYED BY PROGRAMS OR PLANS.—

(1) INDUCEMENTS TO INDIVIDUALS ENROLLED UNDER MEDICARE.—

(A) OFFER OF REMUNERATION.—Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)) is amended—

(i) by striking '', or'' at the end of paragraph (2) and inserting a semicolon;

(ii) by striking the semicolon at the end of paragraph (3) and inserting ''; or''; and

(iii) by inserting after paragraph (3) the following new paragraph:

''(4) offers to or transfers remuneration to any individual eligible for benefits under title XVIII of this Act, or under a State health care program (as defined in section 1128(h)) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVIII, or a State health care program;''.

(B) REMUNERATION DEFINED.—Section 1128A(i) is amended by adding the following new paragraph:

''(6) The term 'remuneration' includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term 'remuneration' does not include the waiver of coinsurance and deductible amounts by a person, if—

''(A) the waiver is not offered as part of any advertisement or solicitation;

''(B) the person does not routinely waive coinsurance or deductible amounts; and

''(C) the person—

''(i) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need;

''(ii) fails to collect coinsurance or deductible amounts after making reasonable collection efforts; or

''(iii) provides for any permissible waiver as specified in section 1128B(b)(3) or in regulations issued by the Secretary.''.

(2) INDUCEMENTS TO EMPLOYEES.—Section 1128A(a) of such Act (42 U.S.C. 1320a–7a(a)), as amended by paragraph (1), is further amended—

(A) by striking ''or'' at the end of paragraph (3);

(B) by striking the semicolon at the end of paragraph (4) and inserting ''; or''; and

(C) by inserting after paragraph (4) the following new paragraph:

''(5) pays a bonus, reward, or any other remuneration, directly or indirectly, to an employee to induce the employee to encourage individuals to seek or obtain covered items or services for which payment may be made under the medicare program, or a State health care program where the amount of

the remuneration is determined in a manner that takes into account (directly or indirectly) the value or volume of any referrals by the employee to the employer for covered items or services;''.

(b) EXCLUDED INDIVIDUAL RETAINING OWNERSHIP OR CONTROL INTEREST IN PARTICIPATING ENTITY.—Section 1128A(a) of such Act, as amended by subsection (a), is further amended—

(1) by striking ''or'' at the end of paragraph (4);

(2) by striking the semicolon at the end of paragraph (5) and inserting ''; or''; and

(3) by inserting after paragraph (5) the following new paragraph:

''(6) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a program under title XVIII or a State health care program in accordance with this subsection or under section 1128 and who, during the period of exclusion, retains a direct or indirect ownership or control interest of 5 percent or more, or an ownership or control interest (as defined in section 1124(a)(3)) in, or who is an officer, director, agent, or managing employee (as defined in section 1126(b)) of, an entity that is participating in a pro-

gram under title XVIII or a State health care program;''.

(c) MODIFICATIONS OF AMOUNTS OF PENALTIES AND ASSESSMENTS.—Section 1128A(a) of such Act (42 U.S.C. 1320a–7a(a)), as amended by subsections (a) and (b), is amended in the matter following paragraph (6)—

(1) by striking ''$2,000'' and inserting ''$10,000'';

(2) by inserting ''; in cases under paragraph (4), $10,000 for each such offer or transfer; in cases under paragraph (5), $10,000 for each such payment; in cases under paragraph (6), $10,000 for each day the prohibited relationship occurs; in cases under paragraph (7), $10,000 per violation'' after ''false or misleading information was given'';

(3) by striking ''twice the amount'' and inserting ''3 times the amount''; and

(4) by inserting ''(or, in cases under paragraphs (4), (5), and (7), 3 times the amount of the illegal remuneration)'' after ''for each such item or service''.

(d) CLAIM FOR ITEM OR SERVICES BASED ON INCORRECT CODING OR MEDICALLY UNNECESSARY SERVICES.—Section 1128A(a)(1) of such Act (42 U.S.C. 1320a–7a(a)(1)) is amended—

(1) in subparagraph (A) by striking ''claimed,'' and inserting the following: ''claimed, including any person who presents or causes to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,'';

(2) in subparagraph (C), by striking ''or'' at the end; and

(3) by inserting after subparagraph (D) the following new subparagraph:

''(E) is for a medical or other item or service that a person knows or should know is not medically necessary; or''.

(e) PERMITTING PARTIES TO BRING ACTIONS ON OWN BEHALF.—Section 1128A of such Act (42 U.S.C. 1320a–7a) is amended by adding at the end the following new subsection:

''(m)(1) Subject to paragraphs (2) and (3), any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that suffers harm or monetary loss as a result of any activity of an individual or entity which makes the individual or entity subject to a civil monetary penalty

under this section may, in a civil action against the individual or entity in the United States District Court, obtain treble damages and costs including attorneys' fees against the individual or entity and such equitable relief as is appropriate.

''(2) A person may bring a civil action under this subsection only if—

''(A) the person provides the Secretary with written notice of—

''(i) the person's intent to bring an action under this subsection,

''(ii) the identities of the individuals or entities the person intends to name as defendants to the action, and

''(iii) all information the person possesses regarding the activity that is the subject of the action that may materially affect the Secretary's decision to initiate a proceeding to impose a civil monetary penalty under this section against the defendants, and

''(B) one of the following conditions is met:

''(i) During the 60-day period that begins on the date the Secretary receives the written notice described in subparagraph (A), the Secretary does not notify the person that the Sec-

retary intends to initiate an investigation to determine whether to impose a civil monetary penalty under this section against the defendants.

''(ii) The Secretary notifies the person during the 60-day period described in clause (i) that the Secretary intends to initiate an investigation to determine whether to impose a civil monetary penalty under this section against the defendants, and the Secretary subsequently notifies the person that the Secretary no longer intends to initiate an investigation or proceeding to impose a civil monetary penalty against the defendants.

''(iii) After the expiration of the 2-year period that begins on the date written notice is provided to the Secretary, the Secretary has not initiated a proceeding to impose a civil monetary penalty against the defendants.

''(3) If a person is awarded any amounts in an action brought under this subsection that are in excess of the damages suffered by the person as a result of the defendant's activities, 20 percent of such amounts shall be withheld from the person for payment into the Anti-Fraud and

Abuse Trust Fund established under section 501(b) of the Advancement of Health Care Reform Act of 1994.

''(4) No action may be brought under this subsection more than 6 years after the date of the activity with respect to which the action is brought.''.

SEC. 515. ACTIONS SUBJECT TO CRIMINAL PENALTIES.

(a) PERMITTING SECRETARY TO IMPOSE CIVIL MONETARY PENALTY.—Section 1128A(b) of the Social Security Act (42 U.S.C. 1320a–7a(a)) is amended by adding the following new paragraph:

''(3) Any person (including any organization, agency, or other entity, but excluding a beneficiary as defined in subsection (i)(5)) who the Secretary determines has violated section 1128(B)(b) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation. In addition, such person shall be subject to an assessment of not more than twice the total amount of the remuneration offered, paid, solicited, or received in violation of section 1128B(b). The total amount of remuneration subject to an assessment shall be calculated without regard to whether some portion thereof also may have been intended to serve a purpose other than one proscribed by section 1128B(b).''.

(b) RESTRICTION ON APPLICATION OF EXCEPTION FOR AMOUNTS PAID TO EMPLOYEES.—Section

1128B(b)(3)(B) of such Act (42 U.S.C. 1320a–7b(b)(3)(B)) is amended by striking ''services;'' and inserting the following: ''services, but only if the amount of remuneration under the arrangement is (i) consistent with fair market value; (ii) not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the employee to the employer for the furnishing (or arranging for the furnishing) of such items or services; and (iii) provided pursuant to an arrangement that would be commercially reasonable even if no referrals were made;''.

SEC. 516. SANCTIONS AGAINST PRACTITIONERS AND PERSONS FOR FAILURE TO COMPLY WITH STATUTORY OBLIGATIONS.

(a) MINIMUM PERIOD OF EXCLUSION FOR PRACTITIONERS AND PERSONS FAILING TO MEET STATUTORY OBLIGATIONS.—

(1) IN GENERAL.—The second sentence of section 1156(b)(1) of the Social Security Act (42 U.S.C. 1320c–5(b)(1)) is amended by striking ''may prescribe)'' and inserting ''may prescribe, except that such period may not be less than 1 year)''.

(2) CONFORMING AMENDMENT.—Section 1156(b)(2) of such Act (42 U.S.C. 1320c–5(b)(2)) is amended by striking ''shall remain'' and inserting

''shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain''.

(b) REPEAL OF ''UNWILLING OR UNABLE'' CONDITION FOR IMPOSITION OF SANCTION.—Section 1156(b)(1) of such Act (42 U.S.C. 1320c–5(b)(1)) is amended—

(1) in the second sentence, by striking ''and determines'' and all that follows through ''such obligations,''; and

(2) by striking the third sentence.

(c) AMOUNT OF CIVIL MONEY PENALTY.—Section 1156(b)(3) of such Act (42 U.S.C. 1320c–5(b)(3)) is amended by striking ''the actual or estimated cost'' and inserting the following: ''up to $10,000 for each instance''.

SEC. 517. INTERMEDIATE SANCTIONS FOR MEDICARE HEALTH MAINTENANCE ORGANIZATIONS.

(a) APPLICATION OF INTERMEDIATE SANCTIONS FOR ANY PROGRAM VIOLATIONS.—

(1) IN GENERAL.—Section 1876(i)(1) of the Social Security Act (42 U.S.C. 1395mm(i)(1)) is amended by striking ''the Secretary may terminate'' and all that follows and inserting the following: ''in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C)

(whichever is applicable) on the eligible organization if the Secretary determines that the organization—

''(A) has failed substantially to carry out the contract;

''(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this section;

''(C) is operating in a manner that is not in the best interests of the individuals covered under the contract; or

''(D) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).''.

(2) OTHER INTERMEDIATE SANCTIONS FOR MISCELLANEOUS PROGRAM VIOLATIONS.—Section 1876(i)(6) of such Act (42 U.S.C. 1395mm(i)(6)) is amended by adding at the end the following new subparagraph:

''(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1) the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

''(i) Civil money penalties of not more than $25,000 for each determination under paragraph (1)

if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

''(ii) Civil money penalties of not more than $10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

''(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.''.

(3) PROCEDURES FOR IMPOSING SANCTIONS.—Section 1876(i) of such Act (42 U.S.C. 1395mm(i)) is amended by adding at the end the following new paragraph:

''(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which—

''(A) the Secretary provides the organization with the opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1);

''(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an entity has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to their attention;

''(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

''(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.''.

(4) CONFORMING AMENDMENTS.—

(A) IN GENERAL.—Section 1876(i)(6)(B) of such Act (42 U.S.C. 1395mm(i)(6)(B)) is amended by striking the second sentence.

(B) PROCEDURAL PROVISIONS.—Section 1876(i)(6) of such Act (42 U.S.C.

1395mm(i)(6)) is further amended by adding at the end the following new subparagraph:

''(D) The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under subparagraph (A) or (B) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).''.

(b) AGREEMENTS WITH PEER REVIEW ORGANIZATIONS.—

(1) REQUIREMENT FOR WRITTEN AGREEMENT.—Section 1876(i)(7)(A) of the Social Security Act (42 U.S.C. 1395mm(i)(7)(A)) is amended by striking ''an agreement'' and inserting ''a written agreement''.

(2) DEVELOPMENT OF MODEL AGENCIES.—Not later than July 1, 1995, the Secretary shall develop a model of the agreement that an eligible organization with a risk-sharing contract under section 1876 of the Social Security Act must enter into with an entity providing peer review services with respect to services provided by the organization under section 1876(i)(7)(A) of such Act.

(3) REPORT BY GAO.—

(A) STUDY.—The Comptroller General shall conduct a study of the costs incurred by

eligible organizations with risk-sharing contracts under section 1876(b) of such Act of complying with the requirement of entering into a written agreement with an entity providing peer review services with respect to services provided by the organization, together with an analysis of how information generated by such entities is used by the Secretary to assess the quality of services provided by such eligible organizations.

(B) REPORT TO CONGRESS.—Not later than July 1, 1997, the Comptroller General shall submit a report to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance and the Special Committee on Aging of the Senate on the study conducted under subparagraph (A).

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to contract years beginning on or after January 1, 1995.

SEC. 518. EFFECTIVE DATE.

Unless specifically provided otherwise, the amendments made by this subtitle shall take effect on January 1, 1995.

Subtitle C—Administrative and Miscellaneous Provisions

SEC. 521. ESTABLISHMENT OF THE HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM.

(a) FINDINGS.—The Congress finds the following:

(1) Fraud and abuse with respect to the delivery of and payment for health care services is a significant contributor to the growing costs of the Nation's health care.

(2) Control of fraud and abuse in health care services warrants greater efforts of coordination than those that can be undertaken by individual States or the various Federal, State, and local law enforcement programs.

(3) There is a national need to coordinate information about health care providers and entities that have engaged in fraud and abuse in the delivery of and payment for health care services.

(4) There is no comprehensive national data collection program for the reporting of public information about final adverse actions against health care providers, suppliers, or licensed health care practitioners that have engaged in fraud and abuse in the delivery of and payment for health care services.

(5) A comprehensive national data collection program for the reporting of public information about final adverse actions will facilitate the enforcement of the provisions of the Social Security Act and other statutes applicable to health care fraud and abuse.

(b) GENERAL PURPOSE.—Not later than January 1, 1995, the Secretary shall establish a national health care fraud and abuse data collection program for the reporting of final adverse actions (not including settlements where no finding of liability has been made) against health care providers, suppliers, or practitioners as required by subsection (c), with access as set forth in subsection (d).

(c) REPORTING OF INFORMATION.—

(1) IN GENERAL.—Each government agency and health care plan shall report any final adverse action (not including settlements where no finding of liability has been made) taken against a health care provider, supplier, or practitioner.

(2) INFORMATION TO BE REPORTED.—The information to be reported under paragraph (1) includes:

(A) The name of any health care provider, supplier, or practitioner who is the subject of a final adverse action.

(B) The name (if known) of any health care entity with which a health care provider, supplier, or practitioner is affiliated or associated.

(C) The nature of the final adverse action.

(D) A description of the acts or omissions and injuries upon which the final adverse action was based, and such other information as the Secretary determines by regulation is required for appropriate interpretation of information reported under this section.

(3) CONFIDENTIALITY.—In determining what information is required to be reported, the Secretary shall establish procedures to assure that the privacy of individuals receiving health care services is appropriately protected.

(4) TIMING AND FORM OF REPORTING.—The information required to be reported under this subsection shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date specified by the Secretary.

(5) TO WHOM REPORTED.—The information required to be reported under this subsection shall be reported to the Secretary.

(d) DISCLOSURE AND CORRECTION OF INFORMATION.—

(1) DISCLOSURE.—With respect to the information about final adverse actions (not including settlements where no findings of liability has been made) reported to the Secretary under this section respecting a health care provider, supplier, or practitioner, the Secretary shall, by regulation, provide for—

(A) disclosure of the information, upon request, to the health care provider, supplier, or licensed practitioner, and

(B) procedures in the case of disputed accuracy of the information.

(2) CORRECTIONS.—Each Government agency and health care plan shall report corrections of information already reported about any final adverse action taken against a health care provider, supplier, or practitioner, in such form and manner that the Secretary prescribes by regulation.

(e) ACCESS TO REPORTED INFORMATION.—

(1) AVAILABILITY.—The information in the health care fraud and abuse data collection program

database shall be available to the public, Federal and State government agencies, and health care plans pursuant to procedures that the Secretary shall provide by regulation.

(2) FEES FOR DISCLOSURE.—The Secretary may establish or approve reasonable fees for the disclosure of information in such database. The amount of such a fee may not exceed the costs of processing the requests for disclosure and of providing such information. Such fees shall be available to the Secretary or, in the Secretary's discretion to the agency designated under this section to cover such costs.

(f) PROTECTION FROM LIABILITY FOR REPORTING.—No person or entity shall be held liable in any civil action with respect to any report made as required by this section, without knowledge of the falsity of the information contained in the report.

(g) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

(1) FINAL ADVERSE ACTION.—The term ''final adverse action'' includes:

(A) Civil judgments against a health care provider in Federal or State court related to the delivery of a health care item or service.

(B) Federal or State criminal convictions related to the delivery of a health care item or service.

(C) Actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, and licensed health care practitioners, including—

(i) formal or official actions, such as revocation or suspension of a license (and the length of any such suspension), reprimand, censure or probation,

(ii) any other loss of license of the provider, supplier, or practitioner, by operation of law, or

(iii) any other negative action or finding by such State or Federal agency that is publicly available information.

(D) Exclusion from participation in Federal or State health care programs.

(E) Any other adjudicated actions or decisions that the Secretary shall establish by regulation.

For purposes of subparagraph (B), the existence of a conviction shall be determined under paragraph (4) of section 1128(j) of the Social Security Act.

(2) GOVERNMENT AGENCY.—The term ''Government agency'' shall include:

(A) The Department of Justice.

(B) The Department of Health and Human Services.

(C) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the Department of Defense and the Department of Veterans Affairs.

(D) State law enforcement agencies.

(E) State medicaid fraud and abuse units.

(F) State or Federal agencies responsible for the licensing and certification of health care providers and licensed health care practitioners.

(3) HEALTH CARE PLAN.—The term ''health care plan'' has the meaning given to such term by section 1128(i) of the Social Security Act.

(4) HEALTH CARE PROVIDER.—The term ''health care provider'' means a provider of services as defined in section 1861(u) of the Social Security Act, and any entity, including a health maintenance organization, group medical practice, or any other entity listed by the Secretary in regulation, that provides health care services.

(5) LICENSED HEALTH CARE PRACTITIONERS.—The terms ''licensed health care practitioner'', ''licensed practitioner'', and ''practitioner'' mean, with respect to a State, an individual who is licensed or otherwise authorized by the State to provide health care services (or any individual who, without authority holds himself or herself out to be so licensed or authorized).

(6) SUPPLIER.—The term ''supplier'' means a supplier of health care items and services described in sections 1819 (a) and (b), and section 1861 of the Social Security Act.

(h) CONFORMING AMENDMENT.—Section 1921(d) of the Social Security Act is amended by inserting ''and section 521 of the Advancement of Health Care Reform Act of 1994'' after ''section 422 of the Health Care Quality Improvement Act of 1986''.

SEC. 522. QUARTERLY PUBLICATION OF ADVERSE ACTIONS TAKEN.

(a) IN GENERAL.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new section:

''QUARTERLY PUBLICATION OF ADVERSE ACTIONS TAKEN

''SEC. 1145. Not later than 30 days after the end of each calendar quarter, the Secretary shall publish in the Federal Register a listing of all final adverse actions

taken during the quarter under this part (including penalties imposed under section 1107, exclusions under section 1128, the imposition of civil monetary penalties under section 1128A, and the imposition of criminal penalties under section 1128B) and under section 1156.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to calendar quarters beginning on or after January 1, 1995.

Subtitle D—Amendments to Criminal Law

SEC. 531. HEALTH CARE FRAUD.

(a) IN GENERAL.—

(1) FINES AND IMPRISONMENT FOR HEALTH CARE FRAUD VIOLATIONS.—Chapter 63 of title 18, United States Code, is amended by adding at the end the following:

''§ 1347. Health care fraud

''(a) Whoever knowingly executes, or attempts to execute, a scheme or artifice—

''(1) to defraud any health care plan or other person, in connection with the delivery of or payment for health care benefits, items, or services; or

''(2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody

or control of, any health care plan, or person in connection with the delivery of or payment for health care benefits, items, or services;

shall be fined under this title or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury (as defined in section 1365(g)(3) of this title), such person shall be imprisoned for life or any term of years.

''(b) For purposes of this section, the term 'health care plan' means a federally funded public program or private program for the delivery of or payment for health care items or services.''.

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 63 of title 18, United States Code, is amended by adding at the end the following:

''1347. Health care fraud.''.

SEC. 532. FORFEITURES FOR FEDERAL HEALTH CARE OFFENSES.

Section 982(a) of title 18, United States Code, is amended by inserting after paragraph (5) the following:

''(6)(A) If the court determines that a Federal health care offense is of a type that poses a serious threat to the health of any person or has a significant detrimental impact on the health care system, the court, in imposing sentence on a person convicted of that offense, shall order that person to forfeit property, real or personal, that—

''(i)(I) is used in the commission of the offense; or

''(II) constitutes or is derived from proceeds traceable to the commission of the offense; and

''(ii) is of a value proportionate to the seriousness of the offense.

''(B) For purposes of this paragraph, the term 'Federal health care offense' means a violation of, or a criminal conspiracy to violate—

''(i) section 1347 of this title;

''(ii) section 1128B of the Social Security Act;

''(iii) sections 287, 371, 664, 666, 1001, 1027, 1341, 1343, or 1954 of this title if the violation or conspiracy relates to health care fraud;

''(iv) section 501 or 511 of the Employee Retirement Income Security Act of 1974, if the violation or conspiracy relates to health care fraud; and

''(v) section 301, 303 (a)(2), or 303 (b) or (e) of the Federal Food, Drug and Cosmetic Act, if the violation or conspiracy relates to health care fraud.''.

SEC. 533. INJUNCTIVE RELIEF RELATING TO FEDERAL HEALTH CARE OFFENSES.

Section 1345(a)(1) of title 18, United States Code, is amended—

(1) by striking ''or'' at the end of subparagraph (A);

(2) by inserting ''or'' at the end of subparagraph (B); and

(3) by adding at the end the following new subparagraph:

''(C) committing or about to commit a Federal health care offense (as defined in section 982(a)(6)(B) of this title);''.

SEC. 534. RACKETEERING ACTIVITY RELATING TO FEDERAL HEALTH CARE OFFENSES.

Section 1961(1) of title 18, United States Code, is amended by inserting ''section 982(a)(6) (relating to Federal health care offenses),'' after ''sections 891–894 (relating to extortionate credit transactions),''.

Subtitle E—Amendments to Civil False Claims Act

SEC. 541. AMENDMENTS TO CIVIL FALSE CLAIMS ACT.

Section 3729 of title 31, United States Code, is amended—

(1) in subsection (a)(7), by inserting ''or to a health care plan,'' after ''property to the Government,'';

(2) in the matter following subsection (a)(7), by inserting ''or health care plan'' before ''sustains because of the act of that person,'';

(3) at the end of the first sentence of subsection (a), by inserting ''or health care plan'' before ''sustains because of the act of the person.'';

(4) in subsection (c)—

(A) by inserting ''the term' after ''section,''; and

(B) by adding at the end the following new sentence: ''The term also includes any request or demand, whether under contract or otherwise, for money or property which is made or presented to a health care plan.''; and

(5) by adding at the end the following new subsection:

''(f) HEALTH CARE PLAN DEFINED.—For purposes of this section, the term 'health care plan' means a federally funded public program for the delivery of or payment for health care items or services.''.

TITLE VI—EXPANDING ACCESS IN RURAL AREAS

SEC. 601. SHORT TITLE.

This title may be cited as the ''Rural Health Innovation Demonstration Act of 1993''.

SEC. 602. RURAL HEALTH EXTENSION NETWORKS.

Title XVII of the Public Health Service Act (42 U.S.C. 300u et seq.) is amended by adding at the end thereof the following new section:

"SEC. 1709. RURAL HEALTH EXTENSION NETWORKS.

''(a) GRANTS.—The Secretary, acting through the Health Resources and Services Administration, may award competitive grants to eligible entities to enable such entities to facilitate the development of networks among rural and urban health care providers to preserve and share health care resources and enhance the quality and availability of health care in rural areas. Such networks may be statewide or regionalized in focus.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

''(1)(A) be a rural health extension network that meets the requirements of subsection (c); or

''(B) be an Area Health Education Center Program;

''(2) prepare and submit to the Secretary an application at such time, in such form and containing such information as the Secretary may require; and

''(3) meet such other requirements as the Secretary determines appropriate.

''(c) NETWORKS.—For purposes of subsection (b)(1)(A), a rural health extension network shall be an association or consortium of three or more rural health care providers, and may include one or more urban health care provider, for the purposes of applying for a grant under this section and using amounts received under such grant to provide the services described in subsection (d).

''(d) SERVICES.—

''(1) IN GENERAL.—An entity that receives a grant under subsection (a) shall use amounts received under such grant to—

''(A) provide education and community decisionmaking support for health care providers in the rural areas served by the network;

''(B) utilize existing health care provider education programs, including but not limited to, the program for area health education centers under section 781, to provide educational services to health care providers and trainees including, but not limited to, physicians, nurses and nursing students in the areas served by the network;

''(C) make appropriately trained facilitators available to health care providers located in the areas served by the network to as-

sist such providers in developing cooperative approaches to health care in such area;

''(D) facilitate linkage building through the organization of discussion and planning groups and the dissemination of information concerning the health care resources where available, within the area served by the network;

''(E) support telecommunications and consultative projects to link rural hospitals and other health care providers, and urban or tertiary hospitals in the areas served by the network; or

''(F) carry out any other activity determined appropriate by the Secretary.

''(2) EDUCATION.—In carrying out activities under paragraph (1)(B), an entity shall support the development of an information and resource sharing system, including elements targeted towards high risk populations and focusing on health promotion, to facilitate the ability of rural health care providers to have access to needed health care information. Such activities may include the provision of training to enable individuals to serve as coordinators of health education programs in rural areas.

''(3) COLLECTION AND DISSEMINATION OF DATA.—The chief executive officer of a State shall designate a State agency that shall be responsible for collecting and regularly disseminating information concerning the activities of the rural health extension networks in that State.

''(e) MATCHING REQUIREMENT.—An entity that receives a grant under subsection (a) shall make available (directly or through donations from public or private entities), non-Federal contributions towards the costs of the operations of the network in an amount equal to the amount of the grant.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for each of the fiscal years 1994 through 1997.

''(g) DEFINITION.—As used in this section and section 1710, the term 'rural health care providers' means health care professionals and hospitals located in rural areas. The Secretary shall ensure that for purposes of this definition, rural areas shall include any area that meets any applicable Federal or State definition of rural area.

''(h) RELATION TO OTHER LAWS.—

''(1) IN GENERAL.—Notwithstanding any provision of the antitrust laws, it shall not be considered

a violation of the antitrust laws for entities to develop and operate networks in accordance with this section.

''(2) DEFINITION.—For purposes of this subsection, the term 'antitrust laws' means—

''(A) the Act entitled 'An Act to protect trade and commerce against unlawful restraints and monopolies', approved July 2, 1890, commonly known as the 'Sherman Act' (26 Stat. 209; chapter 647; 15 U.S.C. 1 et seq.);

''(B) the Federal Trade Commission Act, approved September 26, 1914 (38 Stat. 717; chapter 311; 15 U.S.C. 41 et seq.);

''(C) the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes', approved October 15, 1914, commonly known as the 'Clayton Act' (38 Stat. 730; chapter 323; 15 U.S.C. 12 et seq.; 18 U.S.C. 402, 660, 3285, 3691; 29 U.S.C. 52, 53);

''(D) the Act of June 19, 1936, commonly known as the Robinson-Patman Antidiscrimination Act (15 U.S.C. 13 et seq.); and

''(E) any State antitrust laws that would prohibit the activities described in paragraph (1).''.

SEC. 603. RURAL MANAGED CARE COOPERATIVES.

Title XVII of the Public Health Service Act (42 U.S.C. 300u et seq.) as amended by section 602 is further amended by adding at the end thereof the following new section:

"SEC. 1710. RURAL MANAGED CARE COOPERATIVES.

''(a) GRANTS.—The Secretary, acting through the Health Resources and Services Administration, may award competitive grants to eligible entities to enable such entities to develop and administer cooperatives in rural areas that will establish an effective case management and reimbursement system designed to support the economic viability of essential public or private health services, facilities, health care systems and health care resources in such rural areas.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

''(1) prepare and submit to the Secretary an application at such time, in such form and containing such information as the Secretary may require, including a description of the cooperative that the

entity intends to develop and operate using grant funds; and

''(2) meet such other requirements as the Secretary determines appropriate.

''(c) COOPERATIVES.—

''(1) IN GENERAL.—Amounts provided under a grant awarded under subsection (a) shall be used to establish and operate a cooperative made up of all types of health care providers, hospitals, primary access hospitals, other alternate rural health care facilities, physicians, rural health clinics, rural nurse practitioners and physician assistant practitioners, public health departments and others located in, but not restricted to, the rural areas to be served by the cooperative.

''(2) BOARD OF DIRECTORS.—A cooperative established under paragraph (1) shall be administered by a board of directors elected by the members of the cooperative, a majority of whom shall represent rural providers from the local community and include representatives from the local community. Such members shall serve at the pleasure of such members.

''(3) EXECUTIVE DIRECTOR.—The members of a cooperative established under paragraph (1) shall

elect an executive director who shall serve as the chief operating officer of the cooperative. The executive director shall be responsible for conducting the day to day operation of the cooperative including—

''(A) maintaining an accounting system for the cooperative;

''(B) maintaining the business records of the cooperative;

''(C) negotiating contracts with provider members of the cooperative; and

''(D) coordinating the membership and programs of the cooperative.

''(4) REIMBURSEMENTS.—

''(A) NEGOTIATIONS.—A cooperative established under paragraph (1) shall facilitate negotiations among member health care providers and third party payors concerning the rates at which such providers will be reimbursed for services provided to individuals for which such payors may be liable.

''(B) AGREEMENTS.—Agreements reached under subparagraph (A) shall be binding on the members of the cooperative.

''(C) EMPLOYERS.—Employer entities may become members of a cooperative established

under paragraph (1) in order to provide, through a member third party payor, health insurance coverage for its employees. Deductibles shall only be charged to employees covered under such insurance if such employees receive health care services from a provider that is not a member of the cooperative if similar services would have been available from a member provider.

''(D) MALPRACTICE INSURANCE.—A cooperative established under paragraph (1) shall be responsible for identifying and implementing an affordable malpractice insurance program that shall include a requirement that such cooperative assume responsibility for the payment of a portion of the malpractice insurance premium of providers members.

''(5) MANAGED CARE AND PRACTICE STANDARDS.—A cooperative established under paragraph (1) shall establish joint case management and patient care practice standards programs that health care providers that are members of such cooperative must meet to be eligible to participate in agreements entered into under paragraph (4). Such standards shall be developed by such provider members and

shall be subject to the approval of a majority of the board of directors. Such programs shall include cost and quality of care guidelines including a requirement that such providers make available preadmission screening, selective case management services, joint patient care practice standards development and compliance and joint utilization review.

''(6) CONFIDENTIALITY.—

''(A) IN GENERAL.—Patients records, records of peer review, utilization review, and quality assurance proceedings conducted by the cooperative should be considered confidential and protected from release outside of the cooperative. The provider members of the cooperative shall be indemnified by the cooperative for the good faith participation by such members in such the required activities.

''(B) QUALITY DATA.—Notwithstanding any other provision of law, quality data obtained by a hospital or other member of a cooperative in the normal course of the operations of the hospital or member shall be immune from discovery regardless of whether such data is used for purposes other than peer review or

is disclosed to other members of the cooperative involved.

''(d) LINKAGES.—A cooperative shall create linkages among member health care providers, employers, and payors for the joint consultation and formulation of the types, rates, costs, and quality of health care provided in rural areas served by the cooperative.

''(e) MATCHING REQUIREMENT.—An entity that receives a grant under subsection (a) shall make available (directly or through donations from public or private entities), non-Federal contributions towards the costs of the operations of the network in an amount equal to the amount of the grant.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $15,000,000 for each of the fiscal years 1994 through 1997.

''(g) RELATION TO OTHER LAWS.—

''(1) IN GENERAL.—Notwithstanding any provision of the antitrust laws, it shall not be considered a violation of the antitrust laws for entities to develop and operate cooperatives in accordance with this section.

''(2) DEFINITION.—For purposes of this subsection, the term 'antitrust laws' means—

''(A) the Act entitled 'An Act to protect trade and commerce against unlawful restraints and monopolies', approved July 2, 1890, commonly known as the 'Sherman Act' (26 Stat. 209; chapter 647; 15 U.S.C. 1 et seq.);

''(B) the Federal Trade Commission Act, approved September 26, 1914 (38 Stat. 717; chapter 311; 15 U.S.C. 41 et seq.);

''(C) the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes', approved October 15, 1914, commonly known as the 'Clayton Act' (38 Stat. 730; chapter 323; 15 U.S.C. 12 et seq.; 18 U.S.C. 402, 660, 3285, 3691; 29 U.S.C. 52, 53); and

''(D) the Act of June 19, 1936, commonly known as the Robinson-Patman Antidiscrimination Act (15 U.S.C. 13 et seq.); and

''(E) any State antitrust laws that would prohibit the activities described in paragraph (1).''.

SEC. 604. RURAL MENTAL HEALTH OUTREACH GRANTS.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 209bb–31 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 520C. RURAL MENTAL HEALTH OUTREACH GRANTS.

''(a) IN GENERAL.—The Secretary may award competitive grants to eligible entities to enable such entities to develop and implement a plan for mental health outreach programs in rural areas.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

''(1) prepare and submit to the Secretary an application at such time, in such form and containing such information as the Secretary may require, including a description of the activities that the entity intends to undertake using grant funds; and

''(2) meet such other requirements as the Secretary determines appropriate.

''(c) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applications that place emphasis on mental health services for the elderly or children. Priority shall also be given to applications that involve relationships between the applicant and rural managed care cooperatives.

''(d) MATCHING REQUIREMENT.—An entity that receives a grant under subsection (a) shall make available (directly or through donations from public or private entities), non-Federal contributions towards the costs of the operations of the network in an amount equal to the amount of the grant.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $5,000,000 for each of the fiscal years 1994 through 1997.''.

SEC. 605. AREA HEALTH EDUCATION CENTERS.

(a) STIPENDS FOR PERSONNEL.—Section 746(a) of the Public Health Service Act (42 U.S.C. 293j(a)) is amended by adding at the end thereof the following new paragraph:

''(4) STIPENDS.—

''(A) The Secretary may make award grants under this section to rural communities to enable such communities to provide stipends to physicians, nurses, nurse practitioners, physician assistants, and other health professional trainees to encourage such individuals to provide health care services in such rural communities. In addition, the Secretary may award grants under this section to rural communities to enable such communities to provide stipends to physicians, nurses, nurse practitioners, physician assistants, and other health professionals that are practicing in rural areas to retain such individuals in such areas.

''(B) A community that receives a grant under subparagraph (A) shall make available (directly or through donations from public or private entities), non-Federal contributions towards the costs of the operations of the network in an amount equal to the amount of the grant.''.

(b) REAUTHORIZATION.—Section 746(i)(1)(A) of such Act (42 U.S.C. 293j(i)(1)(A)) is amended by striking out ''$25,000,000'' and all that follows through ''1995'' and inserting in lieu thereof ''$25,000,000 for fiscal year 1993, and $42,000,000 for each of the fiscal years 1994 through 1997''.

TITLE VII—TAX PROVISIONS

SEC. 701. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this subtitle an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

SEC. 702. DEDUCTIONS FOR COSTS OF QUALIFIED HEALTH PLANS.

(a) BUSINESS EXPENSE DEDUCTION FOR HEALTH INSURANCE.—Section 162 (relating to trade or business

expenses) is amended by redesignating subsection (m) as subsection (n) and by inserting after subsection (l) the following new subsection:

''(m) GROUP HEALTH PLANS.—The amount of expenses paid or incurred by an employer for a group health plan or as contributions to an employee's medical savings account shall not be allowed as a deduction under this section unless the plan is a federally qualified health plan (as defined in section 111 of the Advancement of Health Care Reform Act of 1994).''.

(b) PERMANENT EXTENSION AND INCREASE IN HEALTH INSURANCE TAX DEDUCTION FOR SELF-EMPLOYED INDIVIDUALS.—

(1) PERMANENT EXTENSION OF DEDUCTION.—

(A) IN GENERAL.—Subsection (l) of section 162 (relating to special rules for health insurance costs of self-employed individuals) is amended by striking paragraph (6).

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall apply to taxable years beginning after December 31, 1993.

(2) INCREASE IN AMOUNT OF DEDUCTION; INSURANCE PURCHASED MUST MEET CERTAIN STANDARDS.—

(A) INCREASE IN AMOUNT OF DEDUCTION.—Paragraph (1) of section 162(l) is amended—

(i) by striking ''25 percent of'' and inserting ''100 percent of''.

(B) INSURANCE PURCHASED MUST MEET CERTAIN STANDARDS.—Paragraph (2) of section 162(l) is amended by adding at the end the following new subparagraph:

''(C) INSURANCE MUST MEET CERTAIN STANDARDS.—Paragraph (1) shall apply only to insurance which is a qualified health plan.''.

(C) TREATMENT OF MULTIEMPLOYER HEALTH PLANS.—Subsection (l) of section 162 is amended by adding at the end the following new paragraph:

''(6) TREATMENT OF MULTIEMPLOYER HEALTH PLANS.—For purposes of this subsection, an amount paid into a multiemployer health plan (as defined in section 91(d)(7)) shall be deemed to be an amount paid for insurance which constitutes medical care.''.

(c) DEDUCTION FOR PREMIUMS LIMITED TO QUALIFIED HEALTH PLANS.—Subparagraph (C) of section 213(d)(1) (defining medical care) is amended by striking ''for insurance'' and inserting ''for a qualified health plan

(as defined in section 111 of the Advancement of Health Care Reform Act of 1994).''.

(d) EFFECTIVE DATE.—Except as provided in subsection (b)(1)(B), the amendments made by this section shall apply to taxable years beginning after the December 31, 1996.

TITLE VIII—REVENUE PROVISIONS

SEC. 801. DISCRETIONARY SPENDING REDUCTIONS.

Section 601(a)(2) of the Congressional Budget Act of 1974 is amended—

(1) in subparagraph (D) by inserting ''and'' after the semicolon;

(2) by amending subparagraph (E) to read as follows:

''(E) with respect to fiscal years 1995, 1996, 1997, and 1998 for the discretionary category 99.6 percent of the amounts set forth for fiscal year 1994 in the concurrent resolution on the budget for fiscal year 1994 (H. Con. Res. 64, 103d Congress);''; and

(3) by striking subparagraph (F).

S 2153 PCS——2

S 2153 PCS——3

S 2153 PCS——4

S 2153 PCS——5

S 2153 PCS——6

S 2153 PCS——7

S 2153 PCS——8

S 2153 PCS——9

S 2153 PCS——10

S 2153 PCS——11

S 2153 PCS——12

Calendar No. 457

103D CONGRESS
2D SESSION

S. 2153

A BILL

To improve access to quality health care, to reform medical malpractice liability standards, to reduce paperwork and simplify administration of health care claims, to establish safe harbors from the application of the antitrust laws for certain activities of providers of health care services, to prevent fraud and abuse in the health care delivery system, and for other purposes.

JUNE 7, 1994

Read the second time and placed on the calendar